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FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 325

RIN 3064–AE18

Annual Stress Test

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Final rule.

SUMMARY: The Federal Deposit Insurance Corporation (the Corporation or FDIC) is issuing a final rule that implements proposed revisions to regulations regarding the annual stress testing requirements for state nonmember banks and state savings associations with total consolidated assets of more than $10 billion (covered banks). The regulations, which implement section 165(i)(2) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act), require covered banks to conduct annual stress tests, report the results of such stress tests to the Corporation and the Board of Governors of the Federal Reserve System (the Board), and publicly disclose a summary of the results of the required stress tests. The final rule revises the 2016 stress test cycle and for years thereafter to begin on January 1 of the calendar year rather than October 1, as is provided for by the current rule. Additionally, the final rule modifies the ''as of'' dates for financial data (that covered banks will use to perform their stress tests) as well as the reporting dates and public disclosure dates of the annual stress tests for both $10 billion to $50 billion covered banks and over $50 billion covered banks.

DATES: This final rule is effective January 1, 2015.

FOR FURTHER INFORMATION CONTACT: Ryan Sheller, Section Chief, (202) 412–4861, Large Bank Supervision, Division of Risk Management and Supervision; Mark G. Flanigan, Supervisory Counsel, (202) 898–7426, Grace Pyun, Senior Attorney, (202) 898–3609, or Benjamin Klein, Senior Attorney, (202) 898–7027, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC, 20429.

SUPPLEMENTARY INFORMATION:

I. Background

Section 165(i) of the Dodd-Frank Act requires two types of stress tests. Section 165(i)(1) requires the Board to conduct annual stress tests of holding companies with $50 billion or more in total consolidated assets (''supervisory stress tests''). Section 165(i)(2) of the Dodd-Frank Act requires the federal banking agencies to issue regulations requiring financial companies with more than $10 billion in total consolidated assets to conduct annual stress tests themselves (company-run stress tests), and it requires that the implementing regulations issued by each of the federal banking agencies be consistent and comparable with each other. In October 2012, the FDIC, the Office of the Comptroller of the Currency (the OCC), and the Board (collectively the Agencies) issued final rules [1] implementing the company-run stress tests requirements. The FDIC's final rule was codified as part 325, subpart C of the FDIC rules and regulations (the Annual Stress Test rule). The Annual Stress Test rule requires FDIC-insured state nonmember banks and FDIC-insured state-chartered savings associations with total consolidated assets of more than $10 billion to conduct annual stress tests.

Part 325, subpart C identifies two categories of covered banks. The first category includes state nonmember banks and state savings associations that have between $10 billion and $50 billion in total consolidated assets, and the second category includes state nonmember banks and state savings associations with over $50 billion in total consolidated assets.[2] For both categories of covered banks, the company-run stress test must assess the potential impact of different scenarios [3] on the capital of the covered bank and certain related items over a forward-looking, nine-quarter planning horizon, taking into account all relevant exposures and activities.[4]

Part 325, subpart C also provides timeframes for the testing, reporting, and publication of the company-run stress tests, which vary depending on the category into which the covered bank falls. Covered banks use financial data as of September 30 (the ''as of'' date) of the preceding calendar year to make projections that estimate their financial position under the different stress scenarios, and to report and publish the results of their annual stress test in the following calendar year. Covered banks with $10 billion to $50 billion in total assets must report the results of their stress tests by March 31 and publish a summary of their results between June 15 and June 30.[5] Over $50 billion covered banks are required to report the results of their annual stress test by January 5 of each calendar year and publish a summary of their results between March 15 and March 31.[6] These testing, reporting, and publication milestones are consistent across the federal banking agencies' respective annual stress testing rules.

A covered bank that is a consolidated subsidiary of a bank holding company or savings and loan holding company subject to company-run stress test requirements administered by the Board is generally permitted to publish abbreviated disclosures of its annual stress test results with the parent holding company's summary and on the same timeline as the parent holding company.[7] The FDIC requires that specific information be included in the disclosure to reflect the changes in the covered bank's capital ratios and the reasons for those changes.

Since the publication and codification of the Annual Stress Test rule, the Agencies have received feedback from the industry regarding the resource

[1] 77 FR 62417 (Oct. 15, 2012) (FDIC); 77 FR 61238 (October 9, 2012) (OCC); 77 FR 62396 (October 12, 2012) (Board).

[2] 12 CFR 325.202(d).

[3] On an annual basis, prior to the start of the stress testing period and no later than November 15, the FDIC provides to covered banks a minimum of three economic scenarios (baseline, adverse, and severely adverse) and additional scenarios as the FDIC determines appropriate for the covered banks to use in performing their stress tests.

[4] In addition, certain covered banks with significant trading activities (as determined by the FDIC) may be required to include a trading and counterparty component for the scenarios used in their stress tests.

[5] 12 CFR 325.204(a); 325.206(a); 325.207(a).

[6] 12 CFR 325.204(a); 325.206(a); 325.207(a).

[7] 12 CFR 325.207(b).

constraints that covered banks face at the beginning and end of the calendar year arising from competing regulatory and reporting deadlines. Furthermore, the Agencies are aware that conducting stress testing during the last quarter of a calendar year may also make it difficult for covered banks to make timely modifications to strategic and operational plans for the following year that address any issues identified in the company-run stress test results.

For these reasons, on July 1, 2014, the FDIC, in coordination with the Board and the OCC, issued a notice of proposed rulemaking (the NPR) in the **Federal Register** that proposed to modify the dates of the stress test cycle and the corresponding reporting and publication deadlines. The NPR proposed to shift the testing, reporting, and disclosure dates for the 2016 company-run stress test cycle and each annual cycle thereafter.[8] The Corporation is now issuing a final rule modifying the dates of the stress test cycle and the corresponding reporting and publication deadlines as proposed in the NPR, as described further below. The final rule will be consistent with final rules issued by the OCC and Board making the same date modifications to the stress testing cycle, agency reporting, and public disclosure.

II. Comments Received

The NPR solicited public comment on all aspects of the proposed rule. The NPR's comment period ended on September 2, 2014, and the FDIC received five comment letters. Comments were submitted by, or on behalf of, individuals, banks and bank holding companies, and banking and financial services industry trade groups and associations. The commenters generally supported the proposed revisions in the NPR, but also requested additional revisions to the proposed timeline shifts.

The commenters supported the proposed timing shift for the start of the stress test cycles to address the challenges to banking organizations and personnel presented at the end of the calendar year. Some commenters encouraged the FDIC to accelerate implementation of the proposed changes so that the adjusted timeframes apply beginning with the 2015 stress test cycle, rather than with the 2016 stress test cycle. The final rule adopts the proposed revisions to the start of the stress test cycle and related dates, but does not accelerate the implementation of the modified dates. The transition period is necessary to give the FDIC and banking organizations sufficient time to revise reporting schedules and change internal systems. As such, the new timeline will become applicable to the stress testing cycle that begins on January 1, 2016.

Commenters also requested that the FDIC provide stress test scenarios by no later than January 15 of a given calendar year given the compressed timeframe for implementation of stress testing processes. In developing the scenarios, the FDIC seeks to provide covered banks with sufficient time to conduct the annual stress tests, while also ensuring that the scenarios reflect timely data on economic and financial conditions. Under the revised timeline, the FDIC expects to provide stress test scenarios as soon as possible and before the deadlines set by the final rule. Accordingly, the FDIC has adopted this aspect of the proposal without significant change.

Commenters additionally requested that the length of the planning horizon be reduced from nine quarters to eight quarters. The NPR would have shifted the stress testing timeline by one quarter, but would have maintained the nine-quarter planning horizon. The commenters argued that the ninth quarter does not provide additional meaningful information given the incremental uncertainty in projections as they move further into the future, and that eight quarters would still represent two full years of capital planning. The FDIC believes that the ninth quarter period provides meaningful information to the Agencies in assessing the projections of covered banks. Accordingly, the final rule maintains the nine-quarter planning horizon.

Commenters also requested that the Agencies delay incorporation of advanced approaches risk-based capital rules into the annual stress testing process indefinitely. The NPR proposed to revise the testing and reporting dates and did not address the application of the risk-based capital rules. As such, the FDIC believes that technical aspects of projecting risk-based capital requirements under the advanced approaches should be dealt with on a case-by-case basis and through the supervisory process.

III. The Final Rule

After reviewing the comments, the FDIC is issuing this final rule to implement the changes proposed in the NPR to part 325, subpart C of the FDIC Rules and Regulations.

A. Company-Run Stress Test Timelines

Beginning January 1, 2016, the stress testing cycle that, under the previous rule, would have begun on October 1 of a given calendar year, will begin January 1 of a given calendar year. Beginning with the 2016 stress-testing cycle, the final rule requires covered banks to conduct company-run stress tests using financial data as of December 31 of the preceding calendar year, which represents a three-month shift from September 30 in the previous rule. The FDIC will provide the economic scenarios to be used by covered banks in their company-run stress tests no later than February 15, rather than November 15, as is provided under the previous rule. For those certain covered banks with significant amounts of trading activities that are required to include trading and counterparty components in their adverse and severely adverse scenarios, the FDIC will select an ''as of'' date between January 1 and March 1 of a calendar year for the data used in this component. The FDIC will communicate this date to the covered banks no later than March 1.

All $10 billion to $50 billion covered banks will be required to conduct and submit the results of their company-run stress tests to the FDIC by July 31 and publish those results during a period beginning on October 15 and ending October 31. Over $50 billion covered banks will be required to conduct and submit the results of their company-run stress tests to the FDIC by April 5 and publish those results during a period beginning on June 15 and ending on July 15. The April 5 reporting deadline for over $50 billion covered banks is a minor change from the April 7 deadline proposed in the NPR.

Furthermore, a covered bank that is a consolidated subsidiary of a bank holding company or savings and loan holding company that is required to conduct an annual company-run stress test under applicable regulations of the Board may continue to elect to conduct its stress test and report to the FDIC on the same timeline as its parent bank holding company or savings and loan holding company as it had under the previous rule. Under the final rule, however, an over $50 billion covered bank that is a consolidated subsidiary of a holding company that is subject to supervisory stress tests conducted by the Board under 12 CFR part 252 may publish the required summary of its company-run stress test no earlier than the date that the Board publishes the supervisory stress test results for the parent holding company, but no later

[8] 79 FR 37235 (July 1, 2014) (FDIC); 79 FR 37231 (OCC); 79 FR 37420 (Board).

than July 15. In addition, if the Board publishes the supervisory stress test results of the covered bank's parent holding company prior to June 15, then the covered bank may satisfy its publication requirement either through actual publication by the covered bank or through publication by the parent holding company under § 325.207.

B. Applicability

The final rule amends the applicability provisions in § 325.203 of the Annual Stress Test rule to reflect the changed timeline. Previously, a state nonmember bank or state savings association that became a covered bank had to conduct its first annual stress test beginning in the next calendar year after the date the state nonmember bank or state savings association became a covered bank. Under the new 2016 stress testing timeline, if this applicability provision were left unchanged, a state nonmember bank or state savings association that became a covered bank as of September 30 of a given year would have been required to conduct its first stress test on January 1, three months after becoming a covered bank. The final rule provides a minimum of nine months between the date on which a state nonmember bank or state savings association becomes a covered bank and the start date of the stress testing cycle in which the covered bank must conduct its first stress test. To preserve the nine-month minimum, the final rule establishes a March 31 cutoff date. A state nonmember bank or state savings association that becomes a covered bank on or before March 31 of a given year would be required to conduct its first stress test in the next calendar year. For example, a state nonmember bank or state savings association that becomes a covered bank on or before March 31, 2015 would be required to conduct its first stress test in the stress testing cycle beginning January 1, 2016. A state nonmember bank or state savings association that becomes a covered bank after March 31 of a given year would be required to conduct its first stress test in the second calendar year after the date the state nonmember bank or state savings association becomes a covered bank. For example, a state nonmember bank or state savings association that becomes a covered bank on June 30, 2015 would be required to conduct its first stress test in the stress testing cycle beginning January 1, 2017.

TABLE 1—MODIFIED ANNUAL STRESS TEST TIMELINE FOR $10 BILLION TO $50 BILLION COVERED BANKS

Action required "As of" date for financial data	Current rule September 30	Final rule December 31
Distribution of Scenarios for Annual Stress Tests by FDIC.	By November 15	By February 15.
Reporting of Annual Stress Test Results	By March 31	By July 31.
Public Disclosure of Annual Stress Test Results	Between June 15 and June 30	Between October 15 and October 31.

TABLE 2—MODIFIED ANNUAL STRESS TEST TIMELINE FOR OVER $50 BILLION COVERED BANKS

Action required "As of" date for financial data	Current rule September 30	Final rule December 31
Distribution of Scenarios for Annual Stress Tests by FDIC.	By November 15	By February 15.
Reporting of Annual Stress Test Results	By January 5	By April 5.
Public Disclosure of Annual Stress Test Results	Between March 15 and March 31	Between June 15 and July 15, *except no earlier than Board publication of the supervisory stress test results of the covered bank's holding company.*[9]

IV. Administrative Law Matters

A. Paperwork Reduction Act Analysis

In accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521) (''PRA''), the Corporation may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (''OMB'') control number. The FDIC has two stress testing information collections: The Annual Stress Test and Stress Testing Reporting Templates, 3064–0187 and –0189.

The Corporation is revising 12 CFR 325.202, 325.203, 325.204, 325.206, and 325.207 by modifying timelines for the testing, reporting, and disclosure of the annual stress tests for covered banks. The revisions shift by three months the ''as of'' date of the financial data used to conduct company-run stress tests for covered banks from September 30 to December 31. The final rule also shifts the reporting and disclosure deadlines for both $10 billion to $50 billion covered banks and over $50 billion covered banks and provide for a new transition period for those covered banks that become covered under the rule. Additionally, under the final rule, an over $50 billion covered bank that is a consolidated subsidiary of a bank holding company or savings and loan holding company subject to supervisory stress tests conducted by the Board may publish the required summary of its annual stress test results no earlier than the date that the Board publishes the supervisory stress test results of the covered bank's parent holding company, but no later than July 15. The revision of timelines in part 325, subpart C does not revise the FDIC's stress testing information collections of information.

B. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* (RFA), requires that each federal agency either certify that a proposed rule would not, if adopted in final form, have a significant economic impact on a substantial number of small entities or prepare an initial regulatory flexibility analysis of the rule and publish the analysis for comment.[10] The final rule applies only to state nonmember banks and state savings associations with more than $10 billion in total consolidated assets. Under

[9] If the Board releases supervisory stress test results prior to June 15, then the covered bank may release its annual stress test results prior to June 15, but no earlier than the release of the supervisory stress test results and no later than July 15.

[10] *See* 5 U.S.C. 603, 604, and 605.

regulations issued by the Small Business Administration (SBA), a bank or other depository institution is considered ''small'' if it has $550 million or less in assets.[11] As of June 30, 2014, there are approximately 3,268 small state nonmember banks and state savings associations. Since the final rule applies only to twenty-six state nonmember banks and state savings associations with more than $10 billion in total consolidated assets, the Corporation does not expect that the final rule will directly affect a substantial number of small entities. It is hereby certified that this rule will not have a significant economic impact on a substantial number of small entities and therefore, a regulatory flexibility analysis under the RFA is not required.

C. Plain Language

Section 722 of the Gramm-Leach-Bliley Act (Pub. L. 106–102, 113 Stat. 1338, 1471, 12 U.S.C. 4809) requires federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. The Corporation sought to present the proposed rule in a simple and straightforward manner and invited comment on how to make the proposed rule easier to understand. The FDIC received no comments on the use of plain language.

D. Small Business Regulatory Enforcement Fairness Act

The Office of Management and Budget has determined that the final rule is not a ''major rule'' within the meaning of the relevant sections of the Small Business Regulatory Enforcement Fairness Act of 1996 [12] (''SBREFA'').

List of Subjects in 12 CFR Part 325

Administrative practice and procedure, Banks, Banking, Disclosures, Federal Deposit Insurance Corporation, Reporting and recordkeeping requirements, State savings associations, Stress tests.

Authority and Issuance

For reasons stated in the preamble, the Board of Directors of the Federal Deposit Insurance Corporation amends subpart C to part 325 of title 12 of the Code of Federal Regulations as follows:

PART 325—CAPITAL MAINTENANCE

■ 1. Revise the authority citation for part 325 to read as follows:

Authority: 12 U.S.C. 5365(i)(2); 12 U.S.C. 5412(b)(2)(C); 12 U.S.C. 1818, 12 U.S.C. 1819(a)(Tenth), 12 U.S.C. 1831o, and 12 U.S.C. 1831p–1.

■ 2. In § 325.202, add paragraph (m) to read as follows:

§ 325.202 Definitions.

* * * * *

(m) *Stress test cycle* means:

(1) Until October 1, 2015, the period beginning October 1 of a calendar year and ending on September 30 of the following calendar year; and

(2) Beginning October 1, 2015, the period beginning January 1 of a calendar year and ending on December 31 of that year.

■ 3. In § 325.203, revise paragraph (b) to read as follows:

§ 325.203 Applicability.

* * * * *

(b)(1) A state nonmember bank or state savings association that becomes a covered bank after October 15, 2012 and on or before March 31, 2014 shall conduct its first annual stress test under this subpart beginning in the next calendar year after the date the state nonmember bank or state savings association becomes a covered bank.

(2) A state nonmember bank or state savings association that becomes a covered bank after March 31, 2014 and on or before March 31, 2015 shall conduct its first annual stress test under this subpart in the January 1, 2016 stress testing cycle.

(3) A state nonmember bank or state savings association that becomes a covered bank on or before March 31 in years following 2015 shall conduct its first annual stress test under this subpart in the stress testing cycle in the next calendar year after the date the state nonmember bank or state savings association becomes a covered bank. A state nonmember bank or state savings association that becomes a covered bank after March 31 in years following 2015 shall conduct its first annual stress test under this subpart in the second calendar year after the date the state nonmember bank or state savings association becomes a covered bank.

* * * * *

■ 4. Revise § 325.204 to read as follows:

§ 325.204 Annual stress tests required.

(a) *General requirements*—(1) *$10 billion to $50 billion covered bank.* Prior to January 1, 2016, a $10 billion to $50 billion covered bank must conduct a stress test on or before March 31 of each calendar year based on financial data as of September 30 of the preceding calendar year. Beginning January 1, 2016, a $10 billion to $50 billion covered bank must conduct a stress test on or before July 31 of each calendar year based on financial data as of December 31 of the preceding calendar year.

(2) *Over $50 billion covered bank.* Prior to January 1, 2016, an over $50 billion covered bank must conduct a stress test on or before January 5 of each calendar year based on financial data as of September 30 of the preceding calendar year. Beginning January 1, 2016, an over $50 billion covered bank must conduct a stress test on or before April 5 of each calendar year based on financial data as of December 31 of the preceding calendar year.

(b) *Scenarios provided by the Corporation.* In conducting the stress test under this subpart, each covered bank must use the scenarios provided the Corporation. The scenarios provided by the Corporation will reflect a minimum of three sets of economic and financial conditions, including baseline, adverse, and severely adverse scenarios. The Corporation will provide a description of the scenarios required under this section to each covered bank no later than November 15 (for stress test cycle beginning October 1, 2014) or February 15 (for stress test cycle beginning January 1, 2016, and all stress test cycles thereafter) of that calendar year.

(c) *Significant trading activities.* The Corporation may require a covered bank with significant trading activities, as determined by the Corporation, to include trading and counterparty components in its adverse and severely adverse scenarios. The trading and counterparty position data used in these components will be as of a date between October 1 and December 1 (for the stress test cycle beginning October 1, 2014) or between January 1 and March 1 (for the stress test cycle beginning January 1, 2016, and all stress test cycles thereafter) of that calendar year selected by the Corporation and communicated to the covered bank no later than December 1 (for the stress test cycle beginning October 1, 2014) or March 1 (for the stress test cycle beginning January 1, 2016, and all stress test cycles thereafter) of the calendar year.

■ 5. Revise § 325.206(a) to read as follows:

§ 325.206 Required reports of stress test results to the FDIC and the Board of Governors of the Federal Reserve System.

(a) Report required for annual stress test results—(1) *$10 billion to $50 billion covered bank.* Prior to January 1, 2016, a $10 billion to $50 billion covered bank must report to the FDIC and to the Board on or before March 31 the results of the stress test in the

[11] 13 CFR 121.201.

[12] 5 U.S.C. 801, *et seq.*

manner and form specified by the FDIC. Beginning January 1, 2016, a $10 billion to $50 billion covered bank must report to the FDIC and to the Board on or before July 31 the results of the stress test in the manner and form specified by the FDIC.

(2) *Over $50 billion covered bank.* Prior to January 1, 2016, an over $50 billion covered bank must report to the FDIC and to the Board, on or before January 5, the results of the stress test in the manner and form specified by the FDIC. Beginning January 1, 2016, an over $50 billion covered bank must report to the FDIC and to the Board, on or before April 5, the results of the stress test in the manner and form specified by the FDIC.

* * * * *

■ 6. Revise § 325. 207(a) to read as follows:

§ 325.207 Publication of stress test results.

(a) Publication date—(1) *$10 billion to $50 billion covered bank.* (i) Prior to January 1, 2016, a $10 billion to $50 billion covered bank must publish a summary of the results of its annual stress test in the period starting June 15 and ending June 30 (for the stress test cycle beginning October 1, 2014).

(ii) Beginning January 1, 2016, a $10 billion to $50 billion covered bank must publish a summary of the results of its annual stress test in the period starting October 15 and ending October 31 (for the stress test cycle beginning January 1, 2016 and for all stress test cycles thereafter).

(2) *Over $50 billion covered bank.* (i) Prior to January 1, 2016, an over $50 billion covered bank must publish a summary of the results of its annual stress tests in the period starting March 15 and ending March 31 (for the stress test cycle beginning October 1, 2014).

(ii) Beginning January 1, 2016, an over $50 billion covered bank must publish a summary of the results of its annual stress tests in the period starting June 15 and ending July 15 (for the stress test cycle beginning January 1 2016, and for all stress test cycles thereafter) provided:

(A) Unless the Corporation determines otherwise, if the over $50 billion covered bank is a consolidated subsidiary of a bank holding company or savings and loan holding company subject to supervisory stress tests conducted by the Board of Governors of the Federal Reserve System under 12 CFR part 252, then, within the June 15 to July 15 period, such covered bank may not publish the required summary of its annual stress test earlier than the date that the Board of Governors of the Federal Reserve System publishes the supervisory stress test results of the covered bank's parent holding company.

(B) If the Board of Governors of the Federal Reserve System publishes the supervisory stress test results of the covered bank's parent holding company prior to June 15, then such covered bank may publish its stress test results prior to June 15, but no later than July 15, through actual publication by the covered bank or through publication by the parent holding company under paragraph (b) of this section.

* * * * *

Dated at Washington, DC, this 18th day of November 2014.

Federal Deposit Insurance Corporation.

By order of the Board of Directors.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2014–27610 Filed 11–20–14; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2013–0072; Directorate Identifier 2013–NE–04–AD; Amendment 39–18017; AD 2014–23–01]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney Division Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are superseding airworthiness directive (AD) 2013–15–09 for all Pratt & Whitney Division (PW) PW4074, PW4074D, PW4077, PW4077D, PW4084D, PW4090, and PW4090–3 turbofan engine models with certain second-stage high-pressure turbine (HPT) air seals installed. AD 2013–15–09 required initial and repetitive inspections for cracks in second-stage HPT air seals. This new AD expands the applicability of AD 2013–15–09 to include additional part numbers (P/Ns), requires removal of the mating hardware if the second-stage HPT air seal is found with a through-crack, and adds a mandatory terminating action. This AD was prompted by reports of cracking in the original location on two additional P/Ns and reports of through-cracks in a new location in the second-stage HPT air seal. We are issuing this AD to prevent failure of the second-stage HPT air seal, which could lead to uncontained engine failure and damage to the airplane.

DATES: This AD is effective December 26, 2014.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of September 17, 2013 (78 FR 49111, August 13, 2013).

ADDRESSES: For service information identified in this AD, contact Pratt & Whitney Division, 400 Main St., East Hartford, CT 06108; phone: (860) 565–8770; fax: (860) 565–4503. You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call (781) 238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2013–0072; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Jo-Ann Theriault, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7105; fax: 781–238–7199; email: *jo-ann.theriault@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2013–15–09, Amendment 39–17525 (78 FR 49111, August 13, 2013), (''AD 2013–15–09''). AD 2013–15–09 applied to all PW PW4074, PW4074D, PW4077, PW4077D, PW4084D, PW4090, and PW4090–3 turbofan engine models with certain second-stage HPT air seals installed. The NPRM published in the **Federal Register** on June 5, 2014 (79 FR 32500). The NPRM was prompted by reports of through-cracks in a different location on a second-stage HPT air seal, and reports of cracking in the original location in two additional second-stage HPT air seals. Pratt & Whitney developed a redesigned second-stage

HPT air seal that corrects the cracking condition in both locations.

The NPRM proposed to require initial and repetitive inspections for cracks in an expanded population of second-stage HPT air seals, and removal of air seals that fail inspection. The NPRM also proposed to require removal of the mating hardware if the second-stage HPT air seal is found with a through-crack, and a mandatory terminating action to the repetitive inspection requirements. We are issuing this AD to correct the unsafe condition on these products.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the NPRM (79 FR 32500, June 5, 2014) and the FAA's response to each comment.

Request To Correct P/N

All Nippon Airways (ANA), Japan Airlines, United Airlines (UA), and PW requested that we correct the reference in the NPRM (79 FR 32500, June 5, 2014) to the P/N for the second-stage HPT air seal from 50L041 to 54L041.

We agree. We corrected the reference to the second-stage HPT air seal P/N in this AD.

Request To Include Air Seal Detail P/N

UA requested that we include the P/N for the air seal detail in this AD. UA has observed instances where the air seal detail, P/N 54L043, is shown as the P/N for the second-stage HPT air seal.

We disagree. The second-stage HPT air seal is identified as P/N 54L041. It includes air seal detail, P/N 54L043. This AD applies to the entire second-stage HPT air seal, including all of its details. We did not change this AD.

Request To Change Compliance Time

ANA, PW, and UA requested that the compliance interval in paragraph (e)(2)(i) of the NPRM (79 FR 32500, June 5, 2014) be increased from 100 cycles-in-service (CIS) to 1,000 CIS. The commenters indicated that this AD should be consistent with AD 2013–15–09, which specifies that the eddy current inspection (ECI) or initial fluorescent-penetrant inspection (FPI) should be performed within 1,000 cycles after the effective date of the AD.

We agree. Performing an ECI or initial FPI within 1,000 cycles of September 17, 2013, the effective date of AD 2013–15–09, maintains an acceptable level of safety. We changed paragraph (e)(2)(i) of this AD to read: ''Perform an initial eddy current inspection (ECI) for cracks within 1,000 cycles-in-service after September 17, 2013, or before further flight, whichever occurs later.''

Request To Update Service Information

ANA and PW asked that we update the reference to the service information from PW Service Bulletin (SB) No. PW4G–112–A72–332, Revision 2, dated April 9, 2014, to PW SB No. PW4G–112–A72–332, Revision 3, dated June 25, 2014.

We agree. We updated the service information reference in the Related Information paragraph in this AD to reflect the most current revision of SB No. PW4G–112–A72–332.

Request To Include First-Stage HPT Air Seals

ANA requested that first-stage HPT air seals be added to the list of parts that must be removed in paragraph (e)(1)(iii) of this AD. ANA indicated that first-stage HPT air seals are included in the Table of Parts in PW SB No. PW4G–112–72–332. This SB lists parts that must be removed from service if a circumferential crack of any length is found propagated through the web of the forward flange outer diameter of the second-stage HPT air seal.

We disagree. If a crack is found in the second-stage HPT air seal, then the life of mating hardware is adversely affected to the point that the mating hardware must be removed. The first-stage HPT air seal is not a life-limited part like the mating hardware we require to be removed if a crack is found. The first-stage HPT air seal, therefore, may be retained unless it is found damaged in the course of removing the rest of the mating hardware. We did not change this AD.

Request To Develop Tracking Process for Parts Being Removed From Service

UA requested that this AD consider record-keeping for the results of the FPI for second-stage HPT air seals that are being removed from service. UA commented that inspecting parts being removed from service is not common practice and that the burden of showing compliance to this AD rests with the operator and appropriate paper records need to be maintained. While the commenter did not request a specific change to this AD, we regard the comment as a reference to the lack of a standard industry practice for inspecting parts that are being removed from service. This refers to the second-stage HPT air seals, P/N 54L041, which are subject to an FPI after removal from service.

We partially agree. We agree that inspecting parts removed from service for their impact on other parts is not common practice. However, operators must maintain adequate records of the maintenance they perform to show that the product has been properly maintained and is eligible for return to service as airworthy. We disagree that we need to impose additional record keeping requirements on operators to ensure that they comply with their obligation to perform maintenance properly. It is up to each operator to establish its own record-keeping process. We did not change this AD.

Request To Develop Reporting and Tracking Processes for Spare Parts

UA indicated the need for a procedure for determining the serviceability of spare parts, i.e., first-stage HPT hubs, second-stage HPT hubs, and second-stage HPT blade retaining plates, that may have been mated previously to a cracked second-stage HPT air seal. UA noted that the continued serviceability of these spare parts depends on the result of the inspection of the second-stage HPT air seal that the parts were mated to while in service. UA would like procedures established to identify, tag, and mark these spare parts. UA noted that such procedures are not standardized within industry. UA also suggested that PW SB No. PW4G–112–A72–330 be revised to add some kind of marking to notate serviceable spare parts.

We partially agree. We do not find the need to mandate a procedure to track these spare parts. Each operator should establish its own process for tracking its spare parts. We did not change this AD.

We agree, however, that mating hardware previously installed with cracked second-stage HPT air seals is not eligible for installation as airworthy. We changed this AD to establish an installation prohibition to clarify that life-limited parts previously mated to a cracked second-stage HPT air seal, P/N 54L041, cannot be reinstalled. We added Installation Prohibition paragraph (f)(2) to this AD, which states: ''After the effective date of this AD, do not install any spare first-stage HPT hub, second-stage HPT hub, or second-stage HPT blade retaining plate that was previously mated in service to a second-stage HPT air seal, P/N 54L041, that was found to have a through-crack in the front forward fillet radius, into any engine.''

Request To Clarify ECI Requirement

ANA asked that we clarify the requirement for an on-wing ECI of second-stage HPT air seals, P/Ns 50L960 and 50L976. The NPRM (79 FR 32500, June 5, 2014) proposed an on-wing ECI

for second-stage HPT air seal, P/N 54L041, only.

We disagree. We are not requiring an ECI for second-stage HPT air seals, P/Ns 50L960 and 50L976, because the ECI probe is not compatible with the geometry of those P/Ns. Also, removal of these parts at the next piece-part exposure without interim inspections maintains an acceptable level of safety. We did not change this AD.

Agreement With This AD

The Boeing Company expressed support for the NPRM (79 FR 32500, June 5, 2014) as proposed.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously. We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Costs of Compliance

We estimate that this AD affects 116 engines installed on airplanes of U.S. registry. We also estimate that it will take about 5 hours to perform the inspection required by this AD. The average labor rate is $85 per hour. We estimate that two engines will also require removal of the first-stage HPT hub, second-stage HPT hub, and second-stage HPT blade retaining plate. We estimate that parts will cost about $698,920 per engine. Based on these figures, we estimate the total cost of this AD on U.S. operators to be $23,420,020.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2013–15–09, Amendment 39–17525 (78 FR 49111, August 13, 2013), and adding the following new AD:

2014–23–01 Pratt & Whitney Division: Amendment 39–18017; Docket No. FAA–2013–0072; Directorate Identifier 2013–NE–04–AD.

(a) Effective Date

This AD is effective December 26, 2014.

(b) Affected ADs

This AD supersedes AD 2013–15–09, Amendment 39–17525 (78 FR 49111, August 13, 2013).

(c) Applicability

This AD applies to all Pratt & Whitney Division (PW) PW4074, PW4074D, PW4077, PW4077D, PW4084D, PW4090, and PW4090–3 turbofan engine models with second-stage high-pressure turbine (HPT) air seal, part number (P/N) 54L041, 50L960, or 50L976, installed.

(d) Unsafe Condition

This AD was prompted by additional reports of cracking in the second-stage HPT air seal. We are issuing this AD to prevent failure of the second-stage HPT air seal, which could lead to uncontained engine failure and damage to the airplane.

(e) Compliance

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

(1) At the next piece-part exposure after the effective date of this AD, do the following:

(i) Remove from service second-stage HPT air seals, P/Ns 50L960, 50L976, and 54L041.

(ii) Perform a fluorescent-penetrant inspection (FPI) of the second-stage HPT air seal, P/N 54L041, for a through-crack in the front forward fillet radius.

(iii) If a through-crack in the front forward fillet radius is found, remove the first-stage HPT hub, second-stage HPT hub, and second-stage HPT blade retaining plate from service. Do not reinstall the first-stage HPT hub, second-stage HPT hub, or second-stage HPT blade retaining plate into any engine.

(2) For engines with second-stage HPT air seals, P/N 54L041, installed, perform initial and repetitive inspections for cracks on-wing until the part is removed from the engine as follows:

(i) Perform an initial eddy current inspection (ECI) for cracks within 1,000 cycles-in-service after September 17, 2013, or before further flight, whichever occurs later.

(ii) Thereafter, repeat the ECI every 1,200 cycles since last inspection, or fewer, depending on the results of the inspection.

(iii) Use section 4.0 of the appendix of PW Alert Service Bulletin (ASB) No. PW4G–112–A72–330, Revision 2, dated July 11, 2013, to perform the inspection and use paragraph 8 of the Accomplishment Instructions of PW ASB No. PW4G–112–A72–330, Revision 2, dated July 11, 2013, to disposition the results of the inspection.

(f) Installation Prohibition

(1) After the effective date of this AD, do not install any second-stage HPT air seal, P/N 54L041, P/N 50L960, or P/N 50L976, into any engine.

(2) After the effective date of this AD, do not install any spare first-stage HPT hub, second-stage HPT hub, or second-stage HPT blade retaining plate that was previously mated in service to a second-stage HPT air seal, P/N 54L041, that was found to have a through-crack in the front forward fillet radius, into any engine.

(g) Definitions

For the purpose of this AD:

(1) Piece-part exposure is when the second-stage HPT air seal is removed from the engine and fully disassembled.

(2) A through-crack is a crack that has propagated through the thickness of the part and can be seen on both the inner diameter and outer diameter of the front forward fillet radius.

(h) Credit for Previous Actions

(1) If you performed an ECI of the second-stage HPT air seal before the effective date of

this AD, using PW ASB No. PW4G–112–A72–330, Revision 1, dated February 14, 2013, or an earlier version, you have met the requirements of paragraph (e)(2)(i) of this AD.

(2) If you performed an in-shop FPI of the second-stage HPT air seal before the effective date of this AD, you have met the requirements of paragraph (e)(2)(i) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(j) Related Information

(1) For more information about this AD, contact Jo-Ann Theriault, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7105; fax: 781–238–7199; email: *jo-ann.theriault@faa.gov.*

(2) PW Service Bulletin (SB) No. PW4G–112–72–332, Revision 3, dated June 25, 2014, which is not incorporated by reference in this AD, can be obtained from PW, using the contact information in paragraph (k)(3) of this AD. This SB provides guidance on how to replace the second-stage HPT air seal with an air seal that is more resistant to low cycle fatigue cracks.

(k) Material Incorporated by Reference

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

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on September 17, 2013 (78 FR 49111, August 13, 2013).

(i) Pratt & Whitney (PW) Alert Service Bulletin No. PW4G–112–A72–330, Revision 2, dated July 11, 2013.

(ii) Reserved.

(4) For PW service information identified in this AD, contact Pratt & Whitney Division, 400 Main St., East Hartford, CT 06108; phone: 860–565–8770; fax: 860–565–4503.

(5) You may view this service information at FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

(6) You may view this service information at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Burlington, Massachusetts, on October 30, 2014.

Colleen M. D'Alessandro,

Assistant Directorate Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2014–27354 Filed 11–20–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2014–0309; Airspace Docket No. 14–AWP–3]

Amendment of Class E Airspace; Lakeport, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E airspace at Lakeport, CA. Controlled airspace is necessary to accommodate Area Navigation (RNAV) Global Positioning System (GPS) standard instrument approach procedures at Lampson Field. The FAA is taking this action to enhance the safety and management of instrument flight rules (IFR) operations at the airport.

DATES: Effective date, 0901 UTC, January 8, 2015. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.9Y, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/ibr_locations.html.*

FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15. For further information, you can contact the Airspace Policy and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC, 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Richard Roberts, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA, 98057; telephone (425) 203–4517.

SUPPLEMENTARY INFORMATION:

History

On July 23, 2014 the FAA published in the **Federal Register** a notice of proposed rulemaking (NPRM) to amend controlled airspace at Lakeport, CA (79 FR 42723). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. One comment from Martin Breunig was received in favor of the proposal.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9Y, dated August 6, 2014, and effective September 15, 2014, which is incorporated by reference in 14 CFR Part 71.1. The E airspace designations listed in this document will be published subsequently in this Order.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) Part 71 by creating Class E airspace extending upward from 700 feet above the surface within a 4-mile radius of Lampson Field, Lakeport, CA. Controlled airspace is needed for RNAV (GPS) standard instrument approaches and departures. This action enhances the safety and management of IFR operations at the airport.

The FAA has determined this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (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 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. The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the U.S. Code. Subtitle 1, Section 106 discusses 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 modifies controlled airspace at Lampson Field, Lakeport, CA.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion

under the National Environmental Policy Act in accordance with FAA Order 1050.1E, ''Environmental Impacts: Policies and Procedures,'' paragraph 311a. 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.

List 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 14 CFR Part 71 continues to read as follows:

Authority: 49 U.S.C. 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 Part 71.1 of the Federal Aviation Administration Order 7400.9Y, Airspace Designations and Reporting Points, dated August 6, 2014, and effective September 15, 2014 is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AWP CA E5 Lakeport, CA [Amended]

Lampson Field, CA
(Lat. 38°59′26″ N., long. 122°54′03″ W.)
Sutter Lakeside Hospital Heliport, CA Point in Space Coordinates
(Lat. 39°06′09″ N., long. 122°53′19″ W.)

That airspace extending upward from 700 feet above the surface within a 4-mile radius of Lampson Field, and within a 5-mile radius of the Point in Space serving the Sutter Lakeside Hospital Heliport.

Issued in Seattle, Washington, on November 6, 2014.

Christopher Ramirez,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2014–26860 Filed 11–20–14; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 211

[Release No. SAB 115]

Staff Accounting Bulletin No. 115

AGENCY: Securities and Exchange Commission.

ACTION: Publication of Staff Accounting Bulletin.

SUMMARY: This staff accounting bulletin rescinds portions of the interpretive guidance included in the Staff Accounting Bulletin Series in order to make the relevant interpretive guidance consistent with authoritative accounting guidance and Securities and Exchange Commission rules and regulations. Specifically, the staff is updating the Series in order to bring existing guidance into conformity with a recent consensus of the Financial Accounting Standards Board Emerging Issues Task Force, Accounting Standards Update No. 2014–17—Business Combinations (Topic 805): Pushdown Accounting (a consensus of the FASB Emerging Issues Task Force).

DATES: *Effective Date:* November 21, 2014.

FOR FURTHER INFORMATION CONTACT: Christopher D. Semesky, Professional Accounting Fellow, Office of the Chief Accountant, at (202) 551–7678, or Todd E. Hardiman, Associate Chief Accountant, Division of Corporation Finance, at (202) 551–3516, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

SUPPLEMENTARY INFORMATION: The statements in staff accounting bulletins are not rules or interpretations of the Commission, nor are they published as bearing the Commission's official approval. They represent interpretations and practices followed by the Division of Corporation Finance and the Office of the Chief Accountant in administering the disclosure requirements of the Federal securities laws.

Dated: November 18, 2014.

Brent J. Fields,

Secretary.

PART 211—[AMENDED]

Accordingly, Part 211 of Title 17 of the Code of Federal Regulations is amended by adding Staff Accounting Bulletin No. 115 to the table found in Subpart B.

Staff Accounting Bulletin No. 115

This staff accounting bulletin rescinds portions of the interpretive guidance included in the Staff Accounting Bulletin Series in order to make the relevant interpretive guidance consistent with current authoritative accounting and auditing guidance and Securities and Exchange Commission (''Commission'') rules and regulations. Specifically, the staff is updating the Series in order to bring existing guidance into conformity with a recent consensus of the Financial Accounting Standards Board Emerging Issues Task Force, Accounting Standards Update No. 2014–17—Business Combinations (Topic 805): Pushdown Accounting (a consensus of the FASB Emerging Issues Task Force) (ASU No. 2014–17).

The following describes the changes made to the Staff Accounting Bulletin Series that are presented at the end of this release:

1. Topic 5: Miscellaneous Accounting

a. Topic 5.J is removed. This topic provided guidance on the application of the ''push down'' basis of accounting in the separate financial statements of entities acquired in purchase transactions. Under this guidance, when a purchase transaction results in an entity becoming substantially wholly owned,[1] a new basis of accounting should be established in the acquired entity's financial statements to reflect the acquirer's basis in the purchased assets and liabilities. Further, this guidance indicates circumstances when an acquired entity's financial statements should reflect the acquirer's debt, related interest expense, and allocable debt issuance costs, when the acquirer borrows funds to acquire substantially all of the common stock of the acquired entity. ASU No. 2014–17 establishes new guidance on the recognition of a new accounting basis. That guidance provides an option to apply ''push down'' accounting in the separate financial statements of an acquired entity upon the occurrence of an event in which an acquirer obtains control of the acquired entity. In addition, any acquisition-related debt incurred by the acquirer would be recognized in the acquired entity's separate financial statements only if the acquired entity is required to recognize a liability for the debt in accordance with other applicable U.S. generally accepted accounting principles.

Accordingly, the staff hereby amends the Staff Accounting Bulletin Series as follows:

[1] As defined in Rule 1–02(aa) of Regulation S–X.

Note: The text of SAB 115 will not appear in the Code of Federal Regulations.

* * * * *

TOPIC 5: MISCELLANEOUS ACCOUNTING

* * * * *

J. Removed by SAB 115

* * * * *

[FR Doc. 2014–27618 Filed 11–20–14; 8:45 am]

BILLING CODE 8011–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2011–0100; FRL–9918–35-Region 8]

Approval and Promulgation of Air Quality Implementation Plans; Montana; Revisions to the Administrative Rules of Montana—Air Quality, Subchapter 7, Exclusion for De Minimis Changes; Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to correct final rules pertaining to the State of Montana's State Implementation Plan (SIP). On February 13, 2012, EPA took final action to partially approve and partially disapprove SIP revisions and new rules as submitted by the State of Montana on June 25, 2010 and May 28, 2003. EPA subsequently discovered errors in our February 13, 2012 final action related to the materials incorporated by reference and the associated regulatory text that inadvertently reversed portions of our July 8, 2011 final action. EPA is taking final action, under section 110 of the Clean Air Act (CAA).

DATES: This final rule is effective December 22, 2014.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–R08–OAR–2011–0100. All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information may not be publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Air Program, Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street Denver, Colorado 80202–1129. EPA requests you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8:00 a.m. to 4:00 p.m., excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Jaslyn Dobrahner, Air Program, EPA, Region 8, Mail Code 8P–AR, 1595 Wynkoop, Denver, Colorado 80202–1129, (303) 312–6252, *dobrahner.jaslyn@epa.gov.*

SUPPLEMENTARY INFORMATION:

Definitions

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

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

(ii) The initials *ARM* mean or refer to the Administrative Rules of Montana.

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

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

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

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I. Background
II. Response to Comments
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I. Background

In our rule published on February 13, 2012 (77 FR 7531), EPA took final action to partially approve and partially disapprove SIP revisions and new rules as submitted by the State of Montana on June 25, 2010 and May 28, 2003. On page 7534, third column, under the regulatory text in 40 CFR 52.1370(c)(72)(i) Incorporation by reference, paragraph (A), EPA inadvertently incorporated by reference all of Administrative Rules of Montana (ARM), 17.8.740, *Definitions.* We are taking final action to amend the regulatory text in 40 CFR 52.1370(c)(72)(i)(A) to specify that EPA only approved the phrase '', except when a permit is not required under ARM 17.8.745'' in ARM 17.8.740(8)(a) and the phrase '', except as provided in ARM 17.8.745'' in ARM 17.8.740(8)(c). Therefore, the regulatory text in 40 CFR 52.1370(c)(72)(i)(A) reads as set forth in the regulatory text of this final rule.

This correction is consistent with: (1) The preamble of our February 13, 2012 final rule (77 FR 7531, 7534); and (2) the July 8, 2011 final rule (76 FR 40237) and associated regulatory text found in 40 CFR 52.1370(c)(70)(i)(B)(2) where we disapproved the phrase in ARM 17.8.740(2) ''includes a reasonable period of time for startup and shakedown and'' and the definitions in ARM 17.8.740(10) and (14), ''Negligible risk to the public health, safety, and welfare and to the environment'' and ''Routine Maintenance, repair, or replacement,'' respectively. We also confirm that our approval of the phrase ''unless the increase meets the criteria in ARM 17.8.745 for a *de minimis* change not requiring a permit, or'' in 17.8.764(1)(b) of our July 8, 2011 final rule (76 FR 40237) is accurate, while the same phrase in the preamble of the July 8, 2011 and February 13, 2012 final rules is incorrect.

In this action, EPA is also taking final action to correct the associated IBR material for our February 13, 2012 (77 FR 7531) rule by striking out the aforementioned phrases (ARM 17.8.740(2), ARM 17.8.743(1)(c)) and two definitions (ARM 17.8.740(10), ARM 17.8.740(14)) that were inadvertently included in the IBR SIP material from the State's May 28, 2003 submittal.

For more detailed information regarding these February 13, 2012 and July 8, 2011 actions, see 77 FR 7531 and 76 FR 40237.

II. Response to Comments

We did not receive any comments on our August 5, 2014 proposal (79 FR 45393) to correct final rules pertaining to the State of Montana's SIP.

III. Final Action

EPA is taking final action to amend the text in 40 CFR 52.1370(c)(72)(i)(A) to read as follows: ''Administrative Rules of Montana, 17.8.740, *Definitions,* ARM 17.8.740(8)(a), the phrase ', except when a permit is not required under ARM 17.8.745' and ARM 17.8.740(8)(c), the phrase ', except as provided in ARM 17.8.745'; 17.8.743, *Montana Air Quality Permits—When Required,* (except the phrase in 17.8.743(1)(b), 'asphalt concrete plants, mineral crushers, and', and 17.8.743(1)(c)); and 17.8.764, *Administrative Amendment to Permit;* effective 12/27/2002.''

IV. Statutory and Executive Orders Review

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations (42 U.S.C. 7410(k), 40 CFR 52.02(a)). Thus, in reviewing SIP submissions, EPA's role is to approve state choices,

provided that they meet the criteria of the CAA. Accordingly, this final action merely approves some state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

• Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);

• Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

• Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

• Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

• Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999); is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and,

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 20, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See CAA section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

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

Dated: October 8, 2014.

Shaun L. McGrath,

Regional Administrator, Region 8.

For the reasons stated in the preamble, the Environmental Protection Agency amends 40 CFR Part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart BB—Montana

■ 2. Section 52.1370 is amended by revising paragraph (c)(72)(i)(A) to read as follows:

§ 52.1370 Identification of Plan.

* * * * *

(c) * * *

(72)* * *

(i) * * *

(A) Administrative Rules of Montana, 17.8.740, *Definitions,* ARM 17.8.740(8)(a) only, the phrase '', except when a permit is not required under ARM 17.8.745'' and ARM 17.8.740(8)(c) only, the phrase '', except as provided in ARM 17.8.745''; 17.8.743, *Montana Air Quality Permits—When Required,* (except the phrase in 17.8.743(1)(b), ''asphalt concrete plants, mineral crushers, and'', and 17.8.743(1)(c) in its entirety); and 17.8.764, *Administrative Amendment to Permit;* effective 12/27/2002.

* * * * *

[FR Doc. 2014–27505 Filed 11–20–14; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 14–1611]

Radio Broadcasting Services; Various Locations

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Audio Division amends the FM Table of Allotments to remove certain vacant FM allotments that were auctioned in FM Auction 94 that are currently considered authorized stations. We are also removing certain vacant allotments that were auctioned in FM Auction 79, FM Auction 91 and FM Auction 93 that are currently considered authorized stations. FM assignments for authorized stations and reserved facilities will be reflected solely in Media Bureau's Consolidated Database System (CDBS).

DATES: Effective November 21, 2014.

FOR FURTHER INFORMATION CONTACT: Rolanda F. Smith, Media Bureau, (202) 418–2700.

SUPPLEMENTARY INFORMATION: This is a summary of the *Report and Order,* DA 14–1611, adopted November 5, 2014, and released November 6, 2014. The full text of this document is available for inspection and copying during normal business hours in the Commission's Reference Center 445 12th Street SW., Washington, DC 20554. The complete text of this document may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street SW., Room CY–B402, Washington, DC, 20054, telephone 1–800–378–3160 or *www.BCPIWEB.com.* The Commission will not send a copy of this *Report and Order* pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A), because the adopted rules are rules of particular applicability. This document does not contain information collection requirements subject to the Paperwork

Reduction Act of 1995, Public Law 104–13. In addition, therefore, it does not contain any proposed 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).

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

Federal Communications Commission.

Nazifa Sawez,

Assistant Chief, Audio Division, Media Bureau.

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

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

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

§ 73.202 [Amended]

■ 2. Amend § 73.202(b), the Table of FM Allotments, as follows:

■ a. Remove Frisco City, under Alabama, Channel 278A.

■ b. Remove Fredonia, under Arizona, Channel 278C1; Leupp, Channel 293C2; McNary, Channel 249C1; Paulden, Channel 228C3; Channel 281C3 at Peach Springs; and Channel 290C2 at Quartzsite.

■ c. Remove Bearden, under Arkansas, Channel 224A and Lake Village, Channel 278C3.

■ d. Remove Alturas, under California, Channel 268C1 and Channel 277C; Amboy, Channel 284A; Cambria, Channel 293A; Greenfield, Channel 254A; Mecca, Channel 274A; Mojave, Channel 255A; Murrieta, Channel 281A; San Joaquin, Channel 299A; and Wasco, Channel 224A.

■ e. Remove Channel 289A, under Colorado, at Steamboat Springs.

■ f. Remove Lake Park, under Florida, Channel 262A and Silver Springs Shore, Channel 259A.

■ g. Remove Americus, under Georgia, Channel 295A; Homerville, Channel 246A; Plains, Channel 290A; and St. Simons Island, Channel 229C3.

■ h. Remove Altamont, under Illinois, Channel 288A; Cuba, Channel 252A; and West Salem, Channel 266A.

■ i. Remove Americus, under Kansas, Channel 240A and Atwood, Channel 292C0.

■ j. Remove Anacoco, under Louisiana, Channel 276C3; Harrisonburg, Channel 232A; and Oil City, Channel 285A.

■ k. Remove Harrison, under Michigan, Channel 280A and Ludington, Channel 242A.

■ l. Remove Channel 245C0 under Minnesota at Grand Portage.

■ m. Remove Vardaman, under Mississippi, Channel 258A.

■ n. Remove Bunker, under Missouri, Channel 292C3 and Eminence, Channel 281A.

■ o. Remove Cut Bank, under Montana, Channel 265C1.

■ p. Remove Cloudcroft, under New Mexico, Channel 250C1; Taos, Channel 288A; and Taos Pueblo, Channel 292C3.

■ q. Remove Coalgate, under Oklahoma, Channel 242A; Holdenville, Channel 265A; Mooreland, Channel 254A; Okeene, Channel 268C3; Ringwood, Channel 285A; Savanna, Channel 275A; Tipton, Channel 233C3; and Waynoka, Channel 231C2.

■ r. Remove Gearhart, under Oregon, Channel 227A; Ione, Channel 258A; Monument, Channel 280C1; and Prairie City, Channel 272C.

■ s. Remove Edgemont, under South Dakota, Channel 289C1 and Rosebud, Channel 257C.

■ t. Remove Bangs, under Texas, Channel 250C3; Big Lake, Channel 296C2; Comanche, Channel 280A; Crowell, Channel 255C3; Dalhart, Channel 261C; Channel 283A at Encino; Freer, Channel 288A; Channel 284A at Junction; Kermit, Channel 229A; Markham, Channel 283A; Mertzon, Channel 278C2; Premont, Channel 287A; Robert Lee, Channel 289A; Santa Anna, Channel 282A; and Sonora, Channel 237C3 and Channel 272A.

■ u. Remove Beaver, under Utah, Channel 259A.

■ v. Remove Sedro-Woolley, under Washington, Channel 289A and Sequim, Channel 237A.

■ w. Remove Marlinton, under West Virginia, Channel 292A.

■ x. Remove Tigerton, under Wisconsin, Channel 295A.

■ y. Remove Wheatland, under Wyoming, Channel 286A.

[FR Doc. 2014–27535 Filed 11–20–14; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register
Vol. 79, No. 225
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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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2014–0775; Directorate Identifier 2014–NM–046–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Airbus Model A300 B4–600, B4–600R, and F4–600R series airplanes, Model A300 C4–605R Variant F airplanes (collectively called Model A300–600 series airplanes), and Model A310 series airplanes. This proposed AD was prompted by reports of insufficient clearance for the electrical wiring bundles in the leading and trailing edges of the left and right wings. This proposed AD would require installation of new bracket assemblies to ensure adequate clearance between the wiring and the structure, and installation of protective split sleeves as mechanical protection to the electrical harnesses. We are proposing this AD to detect and correct insufficient clearance of electrical wiring bundles located in the leading and trailing edges of the left and right wings, which could lead to chafing damage and arcing, possibly resulting in an on-board fire.

DATES: We must receive comments on this proposed AD by January 5, 2015.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

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

For service information identified in this proposed AD, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2014–0775; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

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

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2014–0775; Directorate Identifier 2014–NM–046–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

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

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2014–0034, dated February 5, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> Following publication of FAA SFAR 88 (Special Federal Aviation Regulation 88) (*http://rgl.faa.gov/Regulatory_and_Guidance_Library%5CrgFAR.nsf/0/EEFB3F94451DC06286256C93004F5E07?OpenDocument*), EASA issued AD 2006–0076 (*http://ad.easa.europa.eu/ad/2006-0076*) requiring inspection and corrective action to improve the explosion risk protection system for the left hand (LH) and right hand (RH) wings on A300, A300–600, A300–600ST and A310 aeroplanes.
>
> For A300–600, A300–600ST and A310 aeroplanes, the required detailed visual inspections of electrical bundles located in the leading and trailing edges of the RH and LH wings and a review of the wing electrical installation on the final assembly line have shown that the wing electrical installation does not comply with the minimum distance inspection criteria to the surrounding structure in a few wing locations.
>
> This condition, if not detected and corrected, could lead to damage on the electrical harnesses and on the surrounding structure.
>
> To address this unsafe condition, Airbus developed an improvement of the wing electrical installation to prevent possible chafing and subsequent damage to the electrical harnesses and surrounding structure.
>
> For the reasons described above, this [EASA] AD requires installation of new bracket assemblies to ensure the clearance between the wiring and the structure, and installation of protective split sleeves as mechanical protection to the electrical harnesses.

You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for

and locating Docket No. FAA–2014–0775.

Relevant Service Information

Airbus has issued Service Bulletin A300–24–6103, Revision 02, including Appendix 01, dated February 7, 2013; and Service Bulletin A310–24–2105, Revision 01, including Appendix 01, dated December 11, 2013. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Costs of Compliance

We estimate that this proposed AD affects 199 airplanes of U.S. registry.

We also estimate that it would take about 37 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Required parts would cost up to $18,000 per product. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $4,207,855, or $21,145 per product.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

3. Will not affect intrastate aviation in Alaska; and

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. Amend § 39.13 by adding the following new airworthiness directive (AD):

Airbus: Docket No. FAA–2014–0775; Directorate Identifier 2014–NM–046–AD.

(a) Comments Due Date

We must receive comments by January 5, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the airplanes identified in paragraphs (c)(1) and (c)(2) of this AD, certificated in any category.

(1) All Airbus Model A300 B4–601, B4–603, B4–620, and B4–622 airplanes; Model A300 B4–605R and B4–622R airplanes; Model A300 F4–605R and F4–622R airplanes; and Model A300 C4–605R Variant F airplanes.

(2) All Airbus Model A310–203, –204, –221, –222, –304, –322, –324, and –325 airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 24, Electrical Power.

(e) Reason

This AD was prompted by reports of insufficient clearance for the electrical wiring bundles in the leading and trailing edges of the left and right wings. We are issuing this AD to detect and correct insufficient clearance of electrical wiring bundles located in the leading and trailing edges of the left and right wings, which could lead to chafing damage and arcing, possibly resulting in an on-board fire.

(f) Compliance

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

(g) Modification

Within 30 months after the effective date of this AD: Modify the electrical routing installation at the right-hand and left-hand wing, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A300–24–6103, Revision 2, including Appendix 01, February 7, 2013; or Airbus Service Bulletin A310–24–2105, Revision 1, including Appendix 01, dated December 11, 2013.

(h) Credit for Previous Actions

This paragraph provides credit for the actions required by paragraph (g) of this AD for Model A310 series airplanes, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A310–24–2105, dated March 20, 2013.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone (425) 227–2125; fax (425) 227–1149. Information may be emailed to: *9–ANM–116–AMOC–REQUESTS@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency

(EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) European Aviation Safety Agency Airworthiness Directive 2014–0034, dated February 05, 2014, for related information. This MCAI may be found in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2014–0775.

(2) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on November 13, 2014.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014–27631 Filed 11–20–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 1

RIN 2900–AO39

Animals on VA Property

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its regulation regarding the presence of animals on VA property. Current VA regulation authorizes the presence of seeing-eye dogs on VA property and other animals as authorized at the discretion of a VA facility head or designee. However, applicable Federal law authorizes the presence of guide dogs and other service animals when these animals accompany individuals with disabilities seeking admittance to buildings or property owned or operated by the Federal Government. This proposed rule would expand the current VA regulation to be consistent with applicable Federal law, and would clarify the authority of a VA facility head or designee to allow nonservice animals to be present on VA property.

DATES: Comments must be received by VA on or before January 20, 2015.

ADDRESSES: Written comments may be submitted through *http://www.Regulations.gov;* by mail or hand delivery to the Director, Regulation Policy and Management (02REG), Department of Veterans Affairs, 810 Vermont Ave. NW., Room 1068, Washington, DC 20420; or by fax to (202) 273–9026. Comments should indicate that they are submitted in response to ''RIN 2900–AO39-Animals on VA Property.'' Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System at *http://www.Regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joyce Edmondson, RN, JD, Patient Care Services (10P4), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (410) 637–4755. (This is not a toll free number).

SUPPLEMENTARY INFORMATION: Pursuant to 38 U.S.C. 901, VA may prescribe rules to provide for the maintenance of law and order and the protection of persons and property on VA property. VA implements this authority in regulations at 38 CFR 1.218 pertaining to security and law enforcement and § 1.220. This proposed rule would amend § 1.218(a)(11) to require VA facilities to permit service animals on VA property consistent with 40 U.S.C. 3103 (section 3103) and Sec. 109, Pub. L. 112–154, 126 Stat. 1165 (2012) (section 109). Section 3103(a) provides that guide dogs or other service animals accompanying individuals with disabilities and especially trained for that purpose shall be admitted to any building or other property owned or controlled by the Federal Government on the same terms and conditions, and subject to the same regulations, as generally govern the admission of the public to the property. Section 109 provides that VA specifically may not prohibit the use of a covered service dog in any VA facility, on any VA property, or in any facility or on any property that receives funding from VA, and further defines a covered service dog as a service dog that has been trained by an entity that is accredited by an appropriate accrediting body that evaluates and accredits organizations which train guide or service dogs. Current 38 CFR 1.218(a)(11), however, reads that dogs and other animals, except seeing-eye dogs, shall not be brought upon property except as authorized by the head of the facility or designee. Our current regulation can be interpreted to allow the head of a VA facility or designee to bar access to all animals other than seeing-eye dogs, which is inconsistent with both section 3103(a) and section 109. We would therefore revise our regulation to be consistent with the requirements in section 3103(a) and section 109. We also note that these revisions would be consistent with the remainder of § 1.218 and § 1.220, as well as consistent with VA regulations that ensure accessibility for programs or activities conducted by VA, 38 CFR 15.101 et al.

The proposed revisions to 38 CFR 1.218(a)(11) would establish nationally applicable criteria regarding the presence of service animals on VA property, to ensure that our regulations cannot be interpreted in a manner that conflicts with section 3103(a), section 109, §§ 1.218 and 1.220, or § 15.101 et al. We note that section 3103(b) specifically authorizes the Secretary of VA to prescribe regulations that are necessary in the public interest to carry out section 3103(a) as it applies to any building or other property subject to VA's jurisdiction, and VA is otherwise authorized to prescribe rules to protect persons and property on VA property under 38 U.S.C. 901.

Consistent with section 3103(a), proposed § 1.218(a)(11)(i) would provide that service animals, as defined in proposed paragraph (a)(11)(viii), must be permitted to be present on VA property when those animals accompany individuals with disabilities and are trained for that purpose. Section 3103(a) refers to animals that are ''trained'' as well as ''educated'' for the purpose of accompanying individuals with disabilities, but we believe our regulation should be revised to only include reference to ''trained'' animals. We are not aware of any intent on the part of Congress in section 3103(a) to distinguish ''trained'' from ''educated'' in the context of the skills a service animal learns for the purposes of assisting individuals with disabilities. Additionally, we believe the concept of training an animal versus educating an animal is more relatable for a majority of the public. We explain later in this proposed rulemaking how the definition of ''service animal'' in proposed paragraph (a)(11)(viii) would be consistent with the definition of ''service animal'' in regulations that implement the Americans with Disabilities Act (ADA), as well as consistent with the meaning of ''covered

service dog'' in section 109. Proposed § 1.218(a)(11)(i) would restate other requirements from section 3103(a), that the service animal must be in a guiding harness or on a leash and under the control of the individual with the disability at all times while on VA property, and that VA is not responsible for the care or supervision of the service animal. Lastly, proposed § 1.218(a)(11)(i) would state that service animal presence on VA property is subject to the same terms, conditions, and regulations as generally govern admission of the public to the property.

Proposed § 1.218(a)(11)(ii) would provide that a service animal will be denied access to VA property or removed from otherwise accessible VA property under certain circumstances. The subsequent bases for removal in proposed § 1.218(a)(11)(ii)(A) through (C) would permit a VA facility head or designee to remove a service animal to maintain the general health and safety of veterans, VA employees, other VA stakeholders, and other service dogs. Pursuant to 38 U.S.C. 901(a)(1), maintaining the health and safety of individuals through security and law enforcement restrictions of presence or activities on VA property is the overriding purpose of § 1.218(a) (see, for instance § 1.218(a)(3) and (a)(5)), and the proposed restrictions in this rulemaking would not conflict with § 1.218 generally or with VA regulations related to accessibility of VA programs for individuals with disabilities under 38 CFR 15.101 et al. These bases for removal are also permitted under section 3103(b), which specifically authorizes the Secretary, VA to prescribe regulations that are necessary in the public interest to carry out section 3103(a) as it applies to any building or other property subject to VA's jurisdiction. These bases for removal are further consistent with section 109 because they would not prohibit the use of service dogs generally, but rather would only limit the presence of service dogs under particular circumstances in which a dog's behavior may be contrary to typical public access standards. A basic level of training is expected of and necessary for service dogs to access public areas, and such training in the least is contemplated by section 109, which provides that VA may not prohibit the use of service dogs if such dogs are ''trained by an entity that is accredited by an appropriate accrediting body.'' Section 109. However, we do not interpret section 109 to further require that service dogs must be trained by any specific entity to access VA property, because section 109 does not define an ''appropriate accrediting body.'' More fundamentally, section 109 does not prohibit VA from granting access to a broader group of service animals than those trained by accredited entities generally (see Section 109 (mandating that VA may not prohibit the use of certain ''covered service dogs,'' but does not mandate that VA must only permit the use of such dogs)). Therefore, we interpret section 109 to only guarantee access to VA property for those service dogs that can dependably behave in accordance with typical public access standards for public settings. Proposed paragraphs 1.218(a)(11)(ii)(A) through (C) identify behaviors not in accordance with typical public access standards for public settings and therefore are the basis for removal, and consequently would not conflict with section 109.

Proposed § 1.218(a)(11)(ii)(A) would provide that a service animal will be removed from VA property if the animal is not under the control of the individual with a disability as required under proposed § 1.218(a)(11)(i). In addition to being consistent with section 109, this restriction would be a restatement of the requirement in section 3103(a), to emphasize the fundamental importance of animal control in public settings. Proposed § 1.218(a)(11)(ii)(B) would indicate that a service animal will be removed from VA property if the animal is not housebroken. We would further indicate that this means the animal must be trained to eliminate its waste in an outdoor area.

Proposed § 1.218(a)(11)(ii)(C) would provide that a service animal will be removed from VA property if the animal otherwise poses a risk to the health or safety of people or other service animals. In determining whether an animal poses such a risk, VA would make an individualized assessment based on objective indications to ascertain the severity of the risk. These indications would either be actions of an animal that typically are followed by acts of aggression, or other external signs that the animal poses a risk to the health or safety of people or other service animals. To prevent any aggressive acts of a service animal for the purpose of maintaining the health and safety of people or other service animals, we would propose in paragraph (a)(11)(ii)(C)(1) specific external indicators that are commonly understood to be followed by aggressive acts of animals, to include growling; biting or snapping; baring its teeth; and lunging. Although we do not expect service animals to behave in such ways, owing to their special behavioral training to not be aggressive in public areas, it is nonetheless imperative that we establish a mechanism to remove an animal that is acting in an aggressive manner.

We propose additional external indicators of disease or bad health in paragraph (a)(11)(ii)(C)(2) that would warrant a service animal being removed from VA property, such as external signs of parasites on a service animal (e.g. fleas or ticks), or other external signs of disease or bad health (e.g. diarrhea or vomiting).

The presence of parasites would pose a threat to the health and safety of others, as many of these types of parasites can be spread easily by brief physical contact and in some instances even by close proximity. Additionally, many of these types of parasites reproduce quickly and in great volume to create infestation conditions that are much more difficult to remediate, versus removing a service animal with visible external parasites. Similarly, vomiting or diarrhea or other external signs of disease or bad health would signal immediate illness or disease that could be communicable to people or other service animals.

We propose certain additional restrictions for service animal access in proposed paragraph (a)(11)(iii), specifically for property under the control of the Veterans Health Administration (VHA property), subject to the same terms, conditions, and regulations as generally govern admission of the public to the property, in accordance with section 3103(a), and also in accordance with VA's authority to prescribe rules to protect persons and property on VA property under 38 U.S.C. 901. VHA properties, as health care settings, must maintain the highest standard of clinical practice for the care of veterans. Therefore, we would authorize restrictions on the right of service animal access arising from patient care, patient safety, or infection control standards just as we restrict the right of members of the public. There are specific areas in VHA facilities where the presence of a member of the public or an animal would tend to compromise patient care, patient safety or infection control. In terms of members of the public, VA may be able to mitigate such risks to patient safety or infection control by imposing certain terms and conditions that would be impossible or impractical to impose upon service animals, such as a requirement to wear protective equipment such as gloves, gowns, or masks in areas where such equipment is required (such as operating rooms, and other critical medical care areas).

Another impossible or impractical requirement to impose upon service animals would be the requirement to remain continuously indoors in intensively monitored settings, such as acute inpatient hospital settings. In such settings, veterans would typically be recovering from an acute medical episode, and would not likely be able to effectively attend to the needs of a service animal (e.g. taking the service animal outside, or feeding or watering the service animal). Staff in these inpatient hospital settings must not be expected to set aside their patient monitoring and care duties to instead attend to the needs of a service animal. Additionally, the immediate needs of veterans in these settings would be most appropriately fulfilled by medical staff and not a service animal (for instance, getting in and out of a hospital bed).

It is not possible to predict with certainty all specific areas on VHA property that would need to restrict the presence of a service animal for patient care, patient safety, and infection control reasons. We therefore propose general language authorizing restrictions based on patient care, patient safety, or infection control considerations as part of standards of good clinical practice, and additionally propose a list of areas within VHA facilities that must restrict the access of service animals. This list would not be exhaustive, but would be comprehensive to provide the public with notice of those areas that typically, because of patient care, patient safety, and infection control standards, may not be accessed by service animals. These areas in proposed § 1.218(a)(11)(iii)(A) through (G) would include: Operating rooms and surgical suites; areas where invasive procedures are being performed; acute inpatient hospital settings (e.g. intensive care units, stabilization units, locked mental health units); decontamination, sterile processing, and sterile storage areas; patient rooms or patient treatment areas where it is indicated that a patient has animal allergies, or has fear or phobia(s) of animals; food preparation areas; and any area where personal protective equipment must be worn. Such restrictions would be consistent with section 3103(b), which authorizes VA to establish regulations necessary in the public interest to carry out section 3103 as it applies to any building or other property subject to VA's jurisdiction, as well as consistent with VA's authority to prescribe rules to protect persons and property on VA property under 38 U.S.C. 901. These restrictions would also be consistent with the mandate in section 109 that VA may not prohibit the use of certain service animals, because service animals would not actually be used by individuals with disabilities in a majority of these medical care areas, or in those areas in which public access generally is not granted. For instance, an individual with a disability would not be using a service animal while the individual was undergoing a surgical procedure; hence, preventing the animal to be present in an operating room or other surgical suite area would not be a prohibition on use, and a service animal restriction in these areas would not violate section 109.

The restriction of service animal access to certain areas of VHA property, as health care settings, is further consistent with regulations that implement title III of the ADA. See 28 CFR 36.302(c)(7). Though the ADA and the regulations implementing the ADA do not apply to agencies of the executive branch such as VA, VA is not prevented from adopting standards similar to those in the ADA when appropriate and applicable. In promulgating § 36.302, the Department of Justice (DOJ) considered a substantial number of public comments regarding service animal access during a comprehensive, multi-staged rulemaking process, culminating in the publication of a final rule at 75 FR 56236, Sept. 15, 2010. We agree with the discussion and rationale used by DOJ in their rulemaking to limit the access of service animals in healthcare settings. Particularly, we agree that, consistent with Centers for Disease Control and Prevention guidance, it is generally appropriate to exclude a service animal from limited-access areas that employ general infection control measures and that require persons to undertake added precautions. Id.

We additionally propose in § 1.218(a)(11)(iv) certain restrictions for service animal access, specifically for property under the control of the National Cemetery Administration (NCA), subject to the same terms, conditions, and regulations as generally govern admission of the public to the property, in accordance with 40 U.S.C. 3103(a). NCA honors veterans and their families with final resting places in national shrines and with lasting tributes that commemorate their service and sacrifice to our Nation. VA's 131 national cemeteries are visited year-round, sometimes by large crowds for special events and ceremonies, and committal services, interments, and other memorials are held on a daily basis across the cemetery system. For these reasons, NCA must provide broad public access to cemetery grounds and facilities with certain limitations to ensure public safety.

It is not possible to predict with certainty all specific areas on NCA property that would need to restrict the presence of a service animal for safety and maintenance reasons. We therefore propose general language authorizing restrictions to ensure that public safety, facilities and grounds care, and maintenance control considerations are not compromised. Additionally, we propose a list of areas within NCA facilities that must restrict public access, including service animals and their owners or handlers, to the same extent that the presence of the general public would be unauthorized. These areas in proposed § 1.218(a)(11)(iv)(A) through (C) would include open interment areas including columbaria, construction or maintenance sites, and grounds keeping and storage facilities. Such restrictions would be consistent with section 3103(a), which ensures access for service animals on Federal property only on the same terms and conditions, and subject to the same regulations, as generally govern the admission of the public. Such restrictions would also be consistent with section 3103(b), which authorizes VA to establish regulations necessary in the public interest to carry out this section as it applies to any building or other property subject to VA's jurisdiction. Lastly, these restrictions would be consistent with section 109, because service animals would not be used by individuals with disabilities in those areas in which public access generally would not be permitted.

Proposed § 1.218(a)(11)(v) would provide that if a service animal is denied access to VA property or removed from VA property subject to proposed § 1.218(a)(11)(ii), or restricted from accessing certain VA property subject to proposed § 1.218(a)(11)(iii) and (a)(11)(iv), that VA would give the individual with a disability the opportunity to obtain services without having the service animal on VA property. This provision would be consistent with the regulations that implement the ADA at 28 CFR 36.302(c)(3), and would be important to ensure that the individual with a disability still receives VA services.

Proposed § 1.218(a)(11)(vi) would provide that, subject to limited requirements in proposed § 1.218(a)(11)(vii), an individual with a disability must not be required to provide documentation, such as proof that an animal has been certified, trained, or licensed as a service animal, to gain access to VA property accompanied by their service animal.

Proposed paragraph (a)(11)(vi) would further state that an individual may be asked if the animal is required because of a disability, and what work or task the animal has been trained to perform. A restriction on required documentation and permitting minimal inquiries would reduce administrative burden for veterans and other VA stakeholders seeking access to VA property, and would prevent VA staff from having to verify documentation that proves service animal training was completed. Proposed paragraph (a)(11)(vi) is consistent with regulations that implement the ADA. See 28 CFR 36.302(c)(6). We agree with the rationale as stated in § 36.302(c)(6) that in most instances, it is apparent that an animal is trained to do work or perform tasks for an individual with a disability. Therefore, restricting documentation and permitting minimal inquiries as proposed in paragraph (a)(11)(vi) should not permit an undue number of nonservice animals to access VA property in contravention of the proposed criteria in this rulemaking.

Proposed § 1.218(a)(11)(vii) would state that an individual with a disability will be required to provide documentation that a service animal is up to date with certain vaccinations and veterinary examinations (as described in proposed paragraphs (a)(11)(vii)(A) and (B)), if such individual will be accompanied by the service animal while receiving treatment in a VHA residential program. This documentation would allow VA to confirm that a service animal was healthy for purposes of continuous, extended exposure to veterans, VA staff, and other VA stakeholders in residential rehabilitation and treatment areas on VHA property (such as VHA Community Living Centers, VHA Mental Health Residential Rehabilitation Treatment Programs, or Blind Rehabilitation Centers). Any additional documentation that would be requested under proposed § 1.218(a)(11)(vii) would only be related to the health and wellness of the animal, and would not be related to an animal's level of training or other certification that the animal was a service animal.

Proposed § 1.218(a)(11)(vii)(A) through (C) would permit VA to request documentation to confirm that a service animal has a current rabies vaccination (1 year or 3 year interval, depending on local requirements), and that a service animal has had a comprehensive physical examination by a licensed veterinarian within the last 12 months that confirms immunizations with core canine vaccines (in addition to the required rabies vaccine) distemper, parvovirus, and adenovirus-2, and screening for and treatment of internal and external parasite as well as control of such parasites. Additionally, the individual with a disability would be asked to confirm in writing that at least seven days have elapsed since the dog recovered from (as applicable), any of the following: vomiting, diarrhea, urinary or fecal incontinence, sneezing or coughing, open wounds, skin infections or mucus membrane infections, orthopedic or other conditions that may interfere with ambulation within the VA facility, and estrus in intact female dogs.

Proposed § 1.218(a)(11)(viii) would define a service animal as any dog that is individually trained to do work and perform tasks for the benefit of an individual with a disability, including a physical, sensory, psychiatric, intellectual, or other mental disability. Other species of animals, whether wild or domestic, trained or untrained, would not be service animals for the purposes of this definition. The work or tasks performed by a service animal would have to be directly related to the individual's disability. The crime deterrent effects of an animal's presence and the provision of emotional support, well-being, comfort, or companionship would not constitute work or tasks for the purposes of this definition. This definition would apply regardless of whether VA is providing benefits to support a service dog under 38 CFR 17.148. We recognize that this definition is broader than the definition of the types of dogs for which we pay benefits under § 17.148; specifically this definition would include service dogs that are trained to mitigate the effects of mental health disabilities (mental health service dogs). We explained in the proposed rulemaking associated with 38 CFR 17.148 that VA does not yet have sufficient evidence to prescribe mental health service dogs as part of a veteran's treatment plan, and therefore cannot at this time offer benefits to support the use of such dogs. 76 FR 35163, June 16, 2011. However, the issue of whether the prescription of mental health service dogs is clinically appropriate to necessitate the provision of benefits under § 17.148 is much narrower than the issue of whether we should allow mental health service dogs to access VA facilities while accompanying individuals with disabilities. Therefore, we believe it is consistent to permit the presence of mental health service dogs on VA property for purposes of ensuring access for individuals with disabilities, while still (at this time) restricting the provision of benefits to support mental health service dogs in § 17.148.

The definition of a ''service animal'' in proposed § 1.218(a)(11)(viii) would be consistent with the definition of ''service animal'' in regulations that implement title III of the ADA. See 28 CFR 36.104. To reiterate, although VA is not bound by the ADA, VA is not prevented from adopting standards similar to those in the ADA when appropriate and applicable. Because there is no existing definition of ''service animal'' in any law or regulation that is applicable to VA, we find the definition in 28 CFR 36.104 the most relevant source for consideration of the issue of service animal presence on VA property, other than those service dogs VA recognizes under § 17.148.

The definition of ''service animal'' in proposed paragraphs (a)(11)(viii) would also be consistent with our interpretation of the definition of a ''covered service dog'' in section 109. We reiterate that we do not interpret section 109 to require that a service dog must be trained by any specific entity, and that section 109 does not prohibit VA from granting access to a broader group of service animals than those trained by accredited entities generally. We would not impose an accreditation requirement to verify that a service dog has been trained appropriately to gain access to VA property.

Proposed § 1.218(a)(11)(viii) would limit dogs as the only species of animal recognized as a service animal, and would further provide that dogs that merely provide crime deterrent effects, emotional support, well-being, comfort, or companionship to individuals (versus being individually trained to assist individuals with disabilities) are not service animals. These limitations are consistent with the current definition of ''service animal'' provided in 28 CFR 36.104. In promulgating § 36.104, DOJ considered a substantial number of public comments regarding species limitations for service animals during a comprehensive, multi-staged rulemaking process, culminating in the publication of the final rule at 75 FR 56236, Sept. 15, 2010. We agree with the discussion and rationale used by DOJ in limiting the definition of a ''service animal'' to only dogs, and to only those dogs that are individually trained to do work and perform tasks for the benefit of an individual with a disability. Specifically, DOJ considered a substantial number of public comments regarding the exclusion of emotional support or companion animals from the definition of ''service animal'' in the regulations implementing the ADA. We agree with the discussion and rationale

used by DOJ in support of this restriction, particularly that the mere presence of a dog that is not trained to perform work or tasks is not required by individuals in the context of public accommodations. In enforcing the ADA, DOJ has been in the unique position since the early 1990s to follow developments regarding service animals, and has determined that only dogs individually trained to assist individuals with disabilities should be defined as a ''service animal'' for consistent admittance to and presence in a variety of public settings. Therefore, we believe it is reasonable to defer to DOJ on these points. We would also not consider service dogs in training to be service animals for purposes of this rule, because such dogs in training have yet to be fully ''trained to do work and perform tasks'' as required in the proposed definition of ''service animal.'' These limitations will provide greater predictability regarding the presence of animals on VA property and facilities, and will reduce risks to the health and safety of those on VA property. It will also allow access to the vast majority of disabled individuals who rely on a service animal to assist them in moving about in public places.

A miniature horse is not included in the definition of a service animal under regulations that implement the ADA. See 28 CFR 36.104. However, 28 CFR 36.302(c)(9)(i) provides that public accommodations must make reasonable modifications in policies, practices, and procedures to permit the use of a miniature horse by an individual with a disability if the miniature horse has been individually trained to do work or perform tasks for the benefit of the individual with a disability. Public accommodation may consider multiple assessment factors under § 36.302(c)(9)(ii) to determine whether allowing a miniature horse access will be a reasonable modification, which include the size and weight of a miniature horse and whether the handler has sufficient control of the horse, whether the miniature horse is housebroken, and whether the horse's presence in a facility would compromise legitimate safety requirements necessary for safe operations. As stated in DOJ's final rule, these assessment factors essentially permit exclusions of miniature horses because they are typically larger and harder to control than service dogs, and can be less predictable in behaving in accordance with typical standards of public access than service dogs. 75 FR 56273. Because we are proposing a definition of ''service animal'' that is so similar to that implemented in ADA regulations, we have also considered the caveat in ADA regulations to permit access of miniature horses in public accommodations. After some consideration, we would exclude the access of miniature horses in this proposed rule because we find their larger size would make them more difficult to control within a facility or remove from a facility as needed. Horses are prey animals and thus have a heightened flee response when they perceive things in their environment as a threat. Coupled with this heightened response, VA healthcare facilities typically have smooth flooring that is able to withstand industrial cleaning and polishing (e.g. vinyl composite tile, polished concrete, etc.), which is difficult for hooved animals to walk on and may contribute to horses having difficulty ambulating or even falling. The presence of a miniature horse in VA facilities is also more likely to be disruptive and may result in egress issues because large numbers of people would likely congregate to see the miniature horse. Additionally, we are not aware that miniature horses generally can be reliably trained to be housebroken in the same manner as service dogs trained to hold their waste until it could be eliminated in outdoor areas. For instance, it would not be appropriate, especially in VA health care facility settings, to permit a miniature horse to eliminate its waste in a specialized waste bag the horse might wear while indoors. All of these factors present too high of a risk to legitimate safety concerns, both to persons and the animal, especially in VA health care facilities, to permit the presence of a miniature horse as a service animal.

Proposed § 1.218(a)(11)(ix) would specify that generally, animals other than service animals are not permitted to be present on VA property, and any individual with a nonservice animal must remove it. Proposed paragraph (a)(11)(ix) would also, however, permit the head of a VA facility or designee to allow certain nonservice animals to be present on VA property for certain reasons. Proposed paragraphs (a)(11)(ix)(A) through (F) would specify the types of nonservice animals that a VA facility head or designee could permit to gain access to VA property.

Proposed § 1.218(a)(11)(ix)(A) would allow, with approval of the VA facility head or designee, nonservice animals to be present on VA property for law enforcement purposes. This exception to the general bar on access for nonservice animals may be required to ensure that the safety of veterans, VA employees, and other VA stakeholders, if a law enforcement team must use animals to conduct investigations, such as explosives detection dogs that would be employed by State or Federal agencies. Proposed § 1.218(a)(11)(ix)(B) would allow, with approval of the VA facility head or designee, nonservice animals to be present on VA property if such animals are under the control of the VA Office of Research and Development (ORD). The use of animals in VA ORD is a privilege granted to those investigators and programs that commit to meeting certain ethical and regulatory standards. VA ORD investigators and programs must follow VA policy on the use of research animals, which incorporates compliance with United States Department of Agriculture Animal Welfare Act Regulations. All VA ORD programs are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care. We note that these and other external standards regarding animal use in VA ORD programs are controlling with regards to the actual criteria contained therein; proposed paragraph (a)(11)(ix)(B) would only establish the authority of a VA facility head to permit these animals to be present on VA property, so that we would not with this rulemaking limit the ability of these types of nonservice animals to be present on VA property.

Proposed § 1.218(a)(11)(ix)(C) through (E) would be related only to property under the control of the Veterans Health Administration (VHA), as the three types of nonservice animals we would designate in these paragraphs would only be relevant for VA health care and hospital settings. Proposed paragraphs (a)(11)(ix)(C) through (E) would therefore contain the same general restrictions relevant to the presence of service animals in certain areas of VHA property, namely that the presence of the animal would only be permitted subject to patient safety, patient care, and infection control standards. Proposed § 1.218(a)(11)(ix)(C) would allow, with approval of the VA facility head or designee, nonservice animals to be present on VHA property if those animals are involved in the provision of animal-assisted therapy (AAT), which is a goal-directed intervention that incorporates the use of an animal into the treatment regimen of a patient, as provided or facilitated by a qualified VA therapist or VA clinician. AAT is designed to improve human physical, social, emotional, and cognitive function, and is provided in a variety of settings and may be group or individual in nature. Clinical disciplines such as physical, occupational, recreational, and

speech therapies use AAT animals to perform tasks that facilitate achievement of patient-specific treatment goals and objectives. Proposed paragraph (a)(11)(ix)(C) would further specify that an AAT animal may be present on VHA property if the animal is used to facilitate achievement of patient-specific treatment goals, as documented in the patient's treatment plan. This requirement would ensure that these types of nonservice animals would be permitted access to VHA property only for the therapeutic benefit of veterans. This proposed paragraph would also specify that an AAT animal must be up to date with all core vaccinations or immunizations, prophylactic medications, and regular health screenings as determined to be necessary by a licensed veterinarian, and that proof of compliance with these requirements is documented and accessible in the area(s) where patients receive AAT. We would require that proof of compliance with these standards be kept in the areas where patients receive AAT, as it is these areas that an AAT animal would be exposed to patients as well as others. Such a requirement would ensure the quickest access to information as needed, to ensure that patient care, patient safety, and infection control standards are not compromised.

Proposed § 1.218(a)(11)(ix)(D) would allow, with approval of the VA facility head or designee, nonservice animals to be present on VHA property if those animals are involved in the provision of animal-assisted activities (AAA), which are activities that involve animals to provide patients with casual opportunities for motivational, educational, recreational, and/or therapeutic benefits. Unlike AAT, AAA is not a goal-directed intervention that is necessarily designed to improve functioning, but that nonetheless may provide opportunities for patients to experience benefits as noted above. AAA does not have to be provided or facilitated by a VA therapist or clinician, and therefore is not necessarily incorporated into the treatment regimen of a patient or documented in the patient's medical record as treatment. Proposed paragraph (a)(11)(ix)(D) would further specify that an AAA animal must be up to date with all required core vaccinations or immunizations, prophylactic medications, and regular health screenings as determined to be necessary by a licensed veterinarian, and that proof of compliance with these requirements is documented and accessible in the area(s) where patients may participate in AAA. We would require that proof of compliance with these standards be kept in the areas where patients may participate in AAA, as it is these areas that an AAA animal would be exposed to patients as well as others. Such a requirement would ensure the quickest access to information as needed, to ensure that patient care, patient safety, and infection control standards are not compromised.

Proposed § 1.218(a)(11)(ix)(E) would allow, with approval of the VA facility head or designee, nonservice animals to be present on VHA property if those animals were present for purposes of a residential animal program in a VA Community Living Center (CLC), which is a long term care setting that provides nursing home care services to veterans, or in a Mental Health Residential Rehabilitation Treatment Program (MHRRTP). Nursing home and mental health care delivery have experienced a significant change in philosophy of care, which has resulted in an initiative to transform the culture of care in VA from a medical model where the care is driven by the medical diagnosis, to a person-centered model where the care is driven by the needs of the individual as impacted by medical conditions. In particular, VA has been working diligently to change the culture of the provision of nursing home care services in its CLCs to create a more homelike environment to foster comfort for veterans while also stimulating a sense of purpose, familiarity, and belonging. The presence of animals is one of many ways that VA seeks to enhance the CLC and MHRRTP environments for veterans. Proposed paragraph (a)(11)(ix)(E) would specify that nonservice animals may be present on VHA property if part of a residential animal program in a VA CLC or a MHRRTP, and would define a residential animal program as a program that uses the presence of animals to create a more homelike environment to foster comfort for veterans, while also stimulating a sense of purpose, familiarity, and belonging. We would state that any VA CLC or MHRRTP residential animal present on VHA property must facilitate achievement of therapeutic outcomes (such as described above), which would be documented in patient treatment plans. We believe this requirement ensures that animals would not be merely residing on a VA CLC or MHRRTP, but rather would be permitted extended access to VHA property only for the therapeutic benefit of veterans. This proposed paragraph would further specify that such an animal must be up to date with all core vaccinations or immunizations, prophylactic medications, and regular health screenings as determined to be necessary by a licensed veterinarian, and that proof of compliance with these requirements must be documented and accessible on the premises of the VA CLC or MHRRTP. This requirement that certain documentation be accessible where the animals are exposed to patients and others is supported by the same rationale as expressed above for AAT animals.

Proposed § 1.218(a)(11)(ix)(F) would allow, with approval of the VA facility head or designee, nonservice animals to be present on NCA property if those animals were present for ceremonial purposes during committal services, interments, and other memorials, if the presence of such animals would not compromise public safety, facilities and grounds care, and maintenance control standards. Such an exception to the general rule for nonservice animals would permit NCA cemeteries and other facilities to honor veterans in line with longstanding military tradition, such as the presence of a horse-drawn caisson for particular services or observances.

Proposed § 1.218(a)(11)(x) would define a disability, for purposes of this section, as ''a physical or mental impairment that substantially limits one or more major life activities of the individual; a record of such an impairment; or being regarded as having such an impairment.'' This definition is consistent with the definition of a disability in 42 U.S.C. 12102, which is applicable to VA through 29 U.S.C. 794, the Rehabilitation Act of 1973. See 29 U.S.C. 794 (a) (defining ''individual with a disability'' by reference to 29 U.S.C. 705(20), which in turn defines ''individual with a disability'' by reference to 42 U.S.C. 12102, for purposes of access to certain programs).

Effect of Rulemaking

The Code of Federal Regulations, as proposed to be revised by this rulemaking, would represent the exclusive legal authority on this subject. No contrary rules or procedures would be authorized. All VA guidance would be read to conform with this proposed rulemaking if possible or, if not possible, such guidance would be superseded by this rulemaking.

Paperwork Reduction Act

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

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would 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. This proposed rule would directly affect only individuals and would not directly affect any small entities. Therefore, under 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604.

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 not to be a significant regulatory action under Executive Order 12866. 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 the 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 FYTD.

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 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 1 year. This proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.007, Blind Rehabilitation Centers; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.011, Veterans Dental Care.

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. Jose D. Riojas, Chief of Staff, Department of Veterans Affairs, approved this document on November 17, 2014, for publication.

List of Subjects in 38 CFR Part 1

Administrative practice and procedure, Cemeteries, Government property, Security measures.

Dated: November 18, 2014.

William F. Russo,

Acting Director, Office of Regulation Policy & Management, Office of the General Counsel, U.S. Department of Veterans Affairs.

For the reasons set out in the preamble, the Department of Veterans Affairs proposes to amend 38 CFR part 1 as follows:

PART 1—GENERAL PROVISIONS

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

Authority: 38 U.S.C. 501(a), and as noted in specific sections.

■ 2. Revise § 1.218(a)(11) to read as follows:

§ 1.218. Security and law enforcement at VA facilities.

(a) * * *

(11) *Animals.* (i) Service animals, as defined in paragraph (a)(11)(viii) of this section, are permitted on VA property when those animals accompany individuals with disabilities and are trained for that purpose. A service animal must be in a guiding harness or on a leash, and under control of the individual with the disability at all times while on VA property. VA is not responsible for the care or supervision of a service animal. Service animal presence on VA property is subject to the same terms, conditions, and regulations as generally govern admission of the public to the property.

(ii) A service animal will be denied access to VA property or removed from VA property if:

(A) The animal is not under the control of the individual with a disability;

(B) The animal is not housebroken. The animal must be trained to eliminate its waste in an outdoor area; or

(C) The animal otherwise poses a risk to the health or safety of people or other service animals. In determining whether an animal poses a risk to the health or safety of people or other service animals, VA will make an individualized assessment based on objective indications to ascertain the severity of the risk. Such indications include but are not limited to:

(*1*) External signs of aggression from the service animal, such as growling, biting or snapping, baring its teeth, lunging; or

(*2*) External signs of parasites on the service animal (e.g. fleas, ticks), or other external signs of disease or bad health (e.g. diarrhea or vomiting).

(iii) Service animals will be restricted from accessing certain areas of VA property under the control of the Veterans Health Administration (VHA property) to ensure patient care, patient safety, or infection control standards are not compromised. Such areas include but are not limited to:

(A) Operating rooms and surgical suites;

(B) Areas where invasive procedures are being performed;

(C) Acute inpatient hospital settings (e.g. intensive care units, stabilization units, locked mental health units);

(D) Decontamination, sterile processing, and sterile storage areas;

(E) Patient rooms or patient treatment areas where it is indicated that a patient has animal allergies, or has fear or phobia(s) of animals;

(F) Food preparation areas; and

(G) Any areas where personal protective equipment must be worn.

(iv) Service animals will be restricted from accessing certain areas of VA

property under the control of the National Cemetery Administration (NCA property) to ensure that public safety, facilities and grounds care, and maintenance control are not compromised. Such areas include but are not limited to:

(A) Open interment areas including columbaria;

(B) Construction or maintenance sites; and

(C) Grounds keeping and storage facilities.

(v) If a service animal is denied access to VA property or removed from VA property in accordance with (a)(11)(ii) of this section, or restricted from accessing certain VA property in accordance with paragraphs (a)(11)(iii) and (iv) of this section, then VA will give the individual with a disability the opportunity to obtain services without having the service animal on VA property.

(vi) Unless paragraph (a)(11)(vii) of this section applies, an individual with a disability must not be required to provide documentation, such as proof that an animal has been certified, trained, or licensed as a service animal, to gain access to VA property accompanied by their service animal. An individual may be asked if the animal is required because of a disability, and what work or task the animal has been trained to perform.

(vii) An individual with a disability will be required to comply with the following requirements, if such individual will be accompanied by the service animal while receiving treatment in a VHA residential program:

(A) The individual with a disability must provide VA with documentation that confirms the service animal has had a current rabies vaccine (one year or three year interval, depending on local requirements);

(B) The individual with a disability must provide VA with documentation that verifies the service animal has had a comprehensive physical exam performed by a licensed veterinarian within the last 12 months that confirms immunizations with the core canine vaccines distemper, parvovirus, and adenovirus-2, and that confirms screening for and treatment of internal and external parasites as well as control of such parasites; and

(C) The individual with a disability must confirm in writing that at least seven days have elapsed since the dog recovered from any instances of vomiting, diarrhea, urinary or fecal incontinence, sneezing or coughing, open wounds, skin infections or mucous membrane infections, orthopedic or other conditions that may interfere with ambulation within the VA facility, and estrus in intact female service dogs.

(viii) A service animal means any dog that is individually trained to do work and perform tasks for the benefit of an individual with a disability, including a physical, sensory, psychiatric, intellectual, or other mental disability. Other species of animals, whether wild or domestic, trained or untrained, are not service animals for the purposes of this definition. The work or tasks performed by a service animal must be directly related to the individual's disability. The crime deterrent effects of an animal's presence and the provision of emotional support, well-being, comfort, or companionship do not constitute work or tasks for the purposes of this definition. Service dogs in training are not considered service animals. This definition applies regardless of whether VA is providing benefits to support a service dog under § 17.148 of this chapter.

(ix) Generally, animals other than service animals (''nonservice animals'') are not permitted to be present on VA property, and any individual with a nonservice animal must remove it. However, a VA facility head or designee may permit certain nonservice animals to be present on VA property for the following reasons:

(A) Animals may be permitted to be present on VA property for law enforcement purposes;

(B) Animals under the control of the VA Office of Research and Development may be permitted to be present on VA property;

(C) Animal-assisted therapy (AAT) animals may be permitted to be present on VHA property, when the presence of such animals would not compromise patient care, patient safety, or infection control standards. AAT is a goal-directed clinical intervention, as provided or facilitated by a VA therapist or VA clinician, that incorporates the use of an animal into the treatment regimen of a patient. Any AAT animal present on VHA property must facilitate achievement of patient-specific treatment goals, as documented in the patient's treatment plan. AAT animals must be up to date with all core vaccinations or immunizations, prophylactic medications, and regular health screenings as determined necessary by a licensed veterinarian, and proof of compliance with these requirements must be documented and accessible in the area(s) where patients receive AAT.

(D) Animal-assisted activity (AAA) animals may be permitted to be present on VHA property, when the presence of such animals would not compromise patient care, patient safety, or infection control standards. AAA involves animals in activities to provide patients with casual opportunities for motivational, educational, recreational, and/or therapeutic benefits. AAA is not a goal-directed clinical intervention that must be provided or facilitated by a VA therapist or clinician, and therefore is not necessarily incorporated into the treatment regimen of a patient or documented in the patient's medical record as treatment. AAA animals must be up to date with all core vaccinations or immunizations, prophylactic medications, and regular health screenings as determined necessary by a licensed veterinarian, and proof of compliance with these requirements must be documented and accessible in the area(s) where patients may participate in AAA.

(E) Animals participating in a VA Community Living Center (CLC) residential animal program or a Mental Health Residential Rehabilitation Treatment Program (MHRRTP) may be permitted to be present on VHA property, when the presence of such animals would not compromise patient care, patient safety, or infection control standards. A residential animal program on a VA CLC or a MHRRTP is a program that uses the presence of animals to create a more homelike environment to foster comfort for veterans, while also stimulating a sense of purpose, familiarity, and belonging. Any VA CLC or MHRRTP residential animal present on VHA property must facilitate achievement of therapeutic outcomes (such as described above), as documented in patient treatment plans. Residential animals on a VA CLC or MHRRTP must be up to date with all core vaccinations and immunizations, prophylactic medications, and regular health screenings as determined necessary by a licensed veterinarian, and proof of compliance with these requirements must be documented and accessible on the VA CLC or MHRRTP.

(F) Animals may be present on NCA property for ceremonial purposes during committal services, interments, and other memorials, if the presence of such animals would not compromise public safety, facilities and grounds care, and maintenance control standards.

(x) For purposes of this section, a disability means a physical or mental impairment that substantially limits one or more major life activities of the individual; a record of such an impairment; or being regarded as having such an impairment.

* * * * *

(Authority: 38 U.S.C. 901, 40 U.S.C. 3103)

[FR Doc. 2014–27629 Filed 11–20–14; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Parts 2800 and 2880

[LLWO301000.L13400000]

RIN 1004–AE24

Competitive Processes, Terms, and Conditions for Leasing Public Lands for Solar and Wind Energy Development and Technical Changes and Corrections

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: On September 30, 2014, the Bureau of Land Management (BLM) published in the **Federal Register** with a 60-day comment period a proposed rule, to facilitate responsible solar and wind energy development and to receive fair market value for such development. *(79 FR 59021)* The proposed rule would promote the use of preferred areas for solar and wind energy development and establish competitive processes, terms, and conditions (including rental and bonding requirements) for solar and wind energy development rights-of-way both inside and outside these preferred areas. The proposed rule would also make technical changes, corrections, and clarifications to existing rights-of-way regulations. Some of these changes would affect all rights-of-way and some provisions would affect particular types of actions, such as transmission lines with a capacity of 100 Kilovolts (kV) or more, or pipelines 10 inches or more in diameter.

The BLM received requests to extend the comment period of this proposed rule. In response to these requests, the BLM is extending the comment period for 15 days beyond the end of the initial comment period. As a result of this extension, the comment period will now close on December 16, 2014.

DATES: Send your comments on this proposed rule to the BLM on or before December 16, 2014. The BLM need not consider, or include in the administrative record for the final rule, comments that the BLM receives after the close of the comment period or comments delivered to an address other than those listed below (see **ADDRESSES**).

ADDRESSES: *Mail:* U.S. Department of the Interior, Director (630), Bureau of Land Management, Mail Stop 2134 LM, 1849 C St. NW., Washington, DC 20240, Attention: 1004–AE24. *Personal or messenger delivery:* Bureau of Land Management, 20 M Street SE., Room 2134 LM, Attention: Regulatory Affairs, Washington, DC 20003. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions at this Web site.

FOR FURTHER INFORMATION CONTACT: Ray Brady, Bureau of Land Management, at 202–912–7312, for information relating to the BLM's solar and wind renewable energy programs, or the substance of the proposed rule. For information pertaining to the changes made for any transmission line with a capacity of 100 kV or more, or any pipeline 10 inches or more in diameter you may contact Lucas Lucero at 202–912–7342. For information on procedural matters or the rulemaking process you may contact Jean Sonneman at 202–912–7405. 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 individuals.

SUPPLEMENTARY INFORMATION:

Public Comment Procedures

If you wish to comment, you may submit your comments by any one of the several methods listed in the **ADDRESSES** section.

Please make your comments as specific as possible by confining them to issues directly related to the content of the proposed rule, and explain the basis for your comments. The comments and recommendations that will be most useful and likely to influence agency decisions are:

1. Those supported by quantitative information or studies; and

2. Those that include citations to, and analyses of, the applicable laws and regulations.

The BLM is not obligated to consider or include in the Administrative Record for the rule comments received after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

Comments, including names and street addresses of respondents, will be available for public review at the address listed under **ADDRESSES** during regular hours (7:45 a.m. to 4:15 p.m.), Monday through Friday, except holidays.

Before including your address, telephone number, email address, or other personal identifying information in your comment, be advised that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask in your comment to withhold from public review your personal identifying information, we cannot guarantee that we will be able to do so.

Janice M. Schneider,

Assistant Secretary, Land and Minerals Management.

[FR Doc. 2014–27639 Filed 11–20–14; 8:45 am]

BILLING CODE 4310–84–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 74

[GN Docket Nos. 14–166 and 12–268; FCC 14–145]

Spectrum Access for Wireless Microphone Operations

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document initiates a proceeding to address how to accommodate the long-term needs of wireless microphone users. Wireless microphones play an important role in enabling broadcasters and other video programming networks to serve consumers, including as they cover breaking news and broadcast live sports events. They enhance event productions in a variety of settings—including theaters and music venues, film studios, conventions, corporate events, houses of worship, and internet webcasts. They also help create high quality content that consumers demand and value. Recent actions by the Commission, and in particular the repurposing of broadcast television band spectrum for wireless services set forth in the *Incentive Auction R&O,* will significantly alter the regulatory environment in which wireless microphones operate, which necessitates our addressing how to accommodate wireless microphone users in the future.

DATES: Comments must be filed on or before January 5, 2015, and reply comments must be filed on or before January 26, 2015.

FOR FURTHER INFORMATION CONTACT: Paul Murray, Office of Engineering and Technology, (202) 418–0688, email: *Paul Murray@fcc.gov,* TTY (202) 418–2989.

ADDRESSES: You may submit comments, identified by GN Docket Nos. 14–166

and 12–268, by any of the following methods:

▪ *Federal Communications Commission's Web site: http://fjallfoss.fcc.gov/ecfs2/.* Follow the instructions for submitting comments.

▪ *Mail:* Paul Murray, Office of Engineering and Technology, Federal Communications Commission, Room 6A162.

▪ *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.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rulemaking,* GN Docket Nos. 14–166 and 16–268, FCC 14–145, adopted September 30, 2014, and released September 30, 2014. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–A257), 445 12th Street SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street SW., Room, CY–B402, Washington, DC 20554. The full text may also be downloaded at: *www.fcc.gov.* Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments 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).

Summary of Notice of Proposed Rulemaking

1. In the Notice of Proposed Rulemaking (*NPRM*), the Commission examines wireless microphone users' needs and technologies that can address them, and seek comment on a variety of existing and new spectrum bands that might accommodate those respective needs. The Commission seeks ways of improving access to the TV band spectrum that remains available for wireless microphones, as well as how to facilitate the transition of wireless microphones out of the 600 MHz Band spectrum repurposed for wireless services. In addition, it examines access to other spectrum bands where wireless microphones currently operate, propose various revisions, and seek comment on potential revisions that may better accommodate wireless microphones in these bands, while protecting the interests of other users that may operate in these bands. Further, the Commission seeks comment on proposals for authorizing wireless microphone operations in additional spectrum bands, consistent with its overall spectrum management goals. The Commission intends to enable the development of a suite of wireless microphone devices and applications, and to provide wireless microphone users with access to spectrum through efficient and effective sharing of the spectrum with other users.

Bands Currently Available for Wireless Microphones

2. Over the years, the Commission has authorized wireless microphone operations in different spectrum bands to accommodate the growing use of these devices by different users. The technical and operational rules for wireless microphone operations in these different bands have varied, depending on the band, and generally are designed to enable wireless microphone users to operate in shared bands along with other users. The Commission has authorized wireless microphones to operate both on a licensed basis, limited to specified users, and on an unlicensed basis.

3. *Recent actions affecting operations in the TV bands.* In recent years, the Commission has taken several actions in three proceedings affecting the TV band spectrum—which have involved the repurposing of UHF TV band spectrum for wireless services in the 700 MHz band (channels 52–69, the 698–806 MHz band), the development of rules for TV White Spaces (TVWS) devices in the TV bands, and the repurposing of the 600 MHz Band that will follow the upcoming incentive auction—that have affected and will affect the future availability of spectrum for wireless microphone uses in these bands. As discussed throughout the *NPRM,* these proceedings inform the instant proceeding, providing the foundation for many of the issues that we are addressing as part of our comprehensive evaluation of how to accommodate wireless microphone uses both in the near and longer term.

4. In January 2010, following the repurposing of TV channels 51–69 in the 700 MHz band for wireless services, the Commission adopted the *TV Bands Wireless Microphones R&O and FNPRM* (WT Dockets 08–166 and 08–167, ET Docket No. 10–24), 75 FR 9113, March 1, 2010, which required that all wireless microphones cease operations on the 700 MHz band no later than June 12, 2010, one year after the end of the DTV transition. In that decision, the Commission also first authorized unlicensed wireless microphone operations in the TV band spectrum (channels 2–51, except channel 37), pursuant to a limited waiver and certain part 15 rules, pending adoption of final rules for unlicensed operations in the TV bands.

5. In September 2010, the Commission adopted the *TV White Spaces Second MO&O,* 75 FR 75814, December 6, 2010, which took several actions that affected the availability of the TV band spectrum for wireless microphones, including adopting rules pursuant to which wireless microphone users and unlicensed TVWS device users would have access to unused TV band channels. Specifically, the Commission provided that the two unused television channels (where

available) nearest channel 37 (above and below) would be designated for wireless microphone operations and not be made available for TVWS devices. The Commission also provided that, to the extent that unused TV channels were available for use by both wireless microphones and TVWS devices at a particular location, licensed wireless microphone operators and certain qualifying unlicensed wireless microphone operators could obtain interference protection from TVWS devices by reserving channels at the specified locations during the times of operation through use of the TV bands databases.

6. In the *Incentive Auction R&O,* 79 FR 48441, August 15, 2014, the Commission adopted rules to implement the broadcast television spectrum incentive auction, which will involve reorganizing the existing television band and repurposing a portion of the UHF television band for new wireless broadband services, and which will affect wireless microphone operations across the current TV bands. The Commission took several actions to accommodate wireless microphone operations, including making rule revisions to provide additional opportunities for wireless microphone operations in the bands that will remain allocated for television following the incentive auction, permitting wireless microphone operations in the newly-designated 600 MHz Band guard bands, and providing for a transition period to give wireless microphone users that will need to cease operating in the spectrum repurposed for 600 MHz Band wireless services sufficient time to replace their equipment and move operations to other spectrum bands available for wireless microphone uses.

7. Finally, concurrent with adoption of the *Incentive Auction R&O,* the Commission adopted the *TV Bands Wireless Microphones Second R&O* to broaden the eligibility for wireless microphone operations in the TV bands to include entities that regularly utilize a substantial number of wireless microphones for large events and productions and which have the same needs for interference protection as existing LPAS licensees. Specifically, the Commission expanded Part 74 LPAS eligibility to include qualifying professional sound companies and operators of large venues that routinely use 50 or more wireless microphones.

8. *Table of bands in which wireless microphones are authorized today.* In the following table, the Commission set forth the bands in which wireless microphones and related audio devices generally operate today pursuant to the Commission's rules.

Frequency band	Licensed/unlicensed	Rule part
26.1–26.48 MHz (VHF)	Licensed	Part 74.
161.625–161.775 MHz (VHF)	Licensed	Part 74.
Portions of 169–172 MHz band (VHF)	Licensed	Part 90.
88–108 MHz (FM)	Unlicensed	Part 15.
450–451, 455–456 MHz (UHF)	Licensed	Part 74.
54–72, 76–88, 174–216, 470–608, 614–698 MHz (VHF and UHF)	Licensed and unlicensed	Part 74 and Part 15 (waiver).
944–952 MHz (UHF)	Licensed	Part 74.
902–928 MHz, 2.4 GHz, 5 GHz (ISM bands)	Unlicensed	Part 15.
1920–1930 MHz (unlicensed PCS)	Unlicensed	Part 15.
Ultra-wideband (3.1–10.6 GHz)	Unlicensed	Part 15.

9. *Additional spectrum resources used by wireless microphone operators.* Apart from operating wireless microphones in the bands where wireless microphones are specifically authorized, as identified in the table above, some wireless microphone users have gained access to other bands for temporary operations under specified conditions. For instance, in recent years professional sound engineering companies providing major event productions (e.g., major sports events) have obtained conditional access to the 1435–1525 MHz band for wireless microphone operations on a temporary, location-specific basis pursuant to time-limited grants of Special Temporary Authority (STA). In seeking temporary access to this spectrum, which is allocated for Aeronautical Mobile Telemetry (AMT) services, these parties have represented that the spectrum resources otherwise available to them at those locations are insufficient to enable them to provide the desired level of coverage for scheduled events, and they must fully coordinate their operations with representatives of the AMT service.

Overview of Operations Today

10. Most wireless microphones users today operate their devices on a secondary basis in the TV bands, with most operations occurring in the UHF TV bands. This use can be attributed to several factors. The TV bands have long been licensed for wireless microphone operations by broadcasters and similar program producers, where they have had access to many unused television channels. In addition, this spectrum has favorable propagation conditions, the signals do not suffer significantly as a result of body loss, antenna sizes are manageable, and there is relatively lower power consumption leading to longer battery life—all of which can be helpful for many wireless microphone purposes. Manufacturers have supplied numerous devices, operating on varying segments of the TV bands that provide a range of users with wireless microphones suitable for their different needs. Although there has at times been a shortage of sufficient available channels in major cities and congested areas, where unused channels are limited and numerous microphones might be needed for particular events, the overall availability of spectrum in the TV bands has enabled wireless microphone users generally to address their needs.

Overall Framework for Addressing Wireless Microphone Needs

11. The Commission seeks to develop a full record and framework for understanding the various needs of different wireless microphone users and the types of microphones that effectively can address those needs.

Users and Uses

12. Given that many different types of users employ wireless microphones in a variety of settings, we seek to develop a more complete record on the various different users of wireless microphones and to better understand their particular needs for wireless microphones. Wireless microphone operations range from professional uses, with the need for numerous high-performance microphones along with other microphones, to the need for a handheld microphone to transmit voice communications, to a range of different

uses and needs for different numbers of microphones in a given setting.

13. The Commission seeks comment on the different groups of wireless microphone operators and their various uses of microphones, including the particular applications served by the microphones, the types and number of devices used, the extent to which the devices are analog or digital, the settings in which they are used, and the frequency bands they use. The Commission asks that the different user groups, or the manufacturers of products for these groups, provide detailed information about the particular nature of wireless microphone uses by different groups of users.

14. The Commission starts by asking for specific information from broadcasters, who have relied heavily on access to the TV bands, regarding their wireless microphone uses and needs. For instance, what are their specific needs for wireless microphones with regard to ENG? What kinds of wireless microphones are used, and to what extent are the TV bands currently used for these microphones? What is the full range of types of devices and applications needed? What is the range of quality of microphones that are needed, in terms of performance quality, voice representation, latency, etc. The Commission asks that commenters discuss the different types of wireless microphones that may be needed in for different applications, including the microphones that need to have high audio quality as well as those that do not require such high fidelity. Recognizing that different numbers of microphones may be used in different settings both in studio and on an itinerant basis, what number of microphones are used in which settings? Do broadcasters make use of bands outside of the TV bands, and if so, in what ways and for what type of applications? The Commission asks commenters to provide information on the range of devices and types of applications that they employ, and the bands in which they operate.

15. Similarly, The Commission requests information from the other licensed users of the TV bands, including movie and cable program producers, other content producers, as well as the newly eligible sound engineering companies and large venue operators, about their uses and needs. It asks for comment on the same types of issues, including current uses, the operational environment in which they may operate, the numbers that may be used, the range in quality of microphones used, the bands used for different wireless microphone applications, etc.

16. In addition the Commission seeks comment from other wireless microphone users, large and small, that use wireless microphones in numerous settings. As discussed, these users include convention and conference centers, corporations, schools, houses of worship, theme parks, music bands, internet webcasts, karaoke bars, and numerous other users. What are their particular wireless microphone uses, what types of devices do they use, the numbers used depending on the settings, in which bands, etc.?

17. As noted, users range from the professional user, who may employ many microphones and coordinate their operations with other uses in the band, to the amateur user who may use only one microphone. We seek general comment on how the Commission should be thinking about these different types of users as it evaluates how to accommodate these users and uses over the long term.

18. The Commission also seeks comment on the nature of the demand for wireless microphones by various wireless microphone users. Have users been employing more wireless microphones in recent years? Has demand for their use changed, and is it growing? It requests that commenters provide a full explanation of the nature of their wireless microphone uses today and what they anticipate their uses will be in the future.

Suitability of Different Bands

19. The Commission seeks comment on additional ways in which it could accommodate various wireless microphone operations in different bands, which include a range of frequencies as low as the television VHF bands and as high as 7 GHz. These bands also vary in terms of potentially available bandwidth, including some with very small channel bandwidth. In addition, some of these bands are available for wireless microphone use only on a licensed basis, while others only an unlicensed basis.

20. The Commission seeks comment on how the nature of different bands, including the propagation features that are associated with them, should inform our consideration of how to accommodate wireless microphones. For what types of applications is lower band spectrum most suitable? What types of uses can be effective in middle or higher frequency bands? How much bandwidth is necessary for different types of wireless microphone uses? What kinds of applications are most suitable for unlicensed operations?

Development, Manufacturing, and Distribution of New Types of Wireless Microphones

21. As the Commission explores how to accommodate wireless microphones uses in different bands, it seeks comment on the factors that manufacturers take into account as they consider and evaluate whether to develop and manufacture new devices for distribution in the near and longer term. The Commission seeks general comment here on these various factors, and expects that commenters also would address these considerations with regard to the discussion specific bands and proposals in Section III of the NPRM.

22. As manufacturers consider developing new wireless microphone devices in different bands, to what extent do the propagation features, the size of band, that potential availability (or lack of availability) of different segments of the band, the extent to which the band allows licensed or unlicensed uses, the technical rules (existing or as revised), the certainty that the band will continue to be available over the long term, or other aspects contribute to the likelihood that new devices will be made for a particular band? What factors do manufactures consider with respect to developing different types of wireless microphones for different users and applications, whether for highest audio quality or for communications that does not require such performance quality? What kinds of economic factors do manufacturers consider? How important are economies of scale? To what extent will manufacturers develop microphones that are designed only for niche markets? To what extent do considerations of the harmonization of potential harmonization of our rules with those of other countries affect a manufacturer's decision to develop new microphones?

23. In addition, assuming the Commission was to adopt revised rules, or make available additional spectrum for access by wireless microphone operators, it seeks comment on manufacturer's expectations regarding the time-to-market for newly developed devices. What factors would enable devices to be developed and introduced quickly into the marketplace? Based on these factors, are certain bands more likely candidates for nearer term introduction of devices than others? What factors would result in introduction of new devices only over the longer term? What are reasonable timelines for the development, manufacture, marketing, and

distribution for new wireless microphones, and what factors contribute to shorter or longer timelines? The Commission invites comment on any other related factors that we should consider.

Transition Issues

24. With the likelihood of there being less UHF television band spectrum available for wireless microphone operators following the incentive auction, the Commission invites general comment on a range issues affecting transitioning of wireless microphone users—whether to the use of different devices operating outside of repurposed 600 MHz Band spectrum, or the use of devices in different bands that can effectively serve their needs in a more efficient fashion.

25. Although the precise amount of TV bands spectrum that will be repurposed will be known only following the auction, we anticipate that many wireless microphone users will need to move their operations out of the repurposed spectrum no later than 39 months following issuance of the *Channel Reassignment PN.* At the same time, many wireless microphone users accessing spectrum that may remain allocated for television services may seek to transition to different devices, including more efficient digital devices, or replace older devices, that may operate both in the bands likely to remain allocated for television or in other bands. The Commission invites comment on these transition issues, the extent to which they are interrelated, and how best to ensure that wireless microphone users transition to new, more efficient devices to the full extent possible.

26. What types of actions would facilitate the transitions that will be required in order to accommodate different wireless microphone operators' needs over the long term? As the Commission considers these various transition issues, what lessons might be drawn from the transition of wireless microphone operations out of the 700 MHz band following the repurposing of that band? How can we best communicate the nature of the transitions along with the necessary actions users must undertake to the large community of disparate microphone users? What timeframes are needed for users of various size and sophistication to plan for, purchase, and install new systems? How is this affected by users' decisions to remain in the TV bands or to migrate to other bands and types of microphones?

27. What actions should the Commission, wireless microphone manufacturers and distributors, and organizations representing wireless microphone users take to facilitate a smooth transition out of the repurposed 600 MHz Band, and to promote the use of more efficient devices to the extent possible, including devices that operate outside of the TV bands? For instance, should users be encouraged to transition their operations to new devices that meet their needs in a more efficient manner, such as digital devices? Is there a particular role that the Commission should play in helping inform consumers of these transitions and the types of devices in different bands that can accommodate their respective needs?

28. As the Commission considers these transition issues, it requests information on the timeframes that may be necessary for design, manufacture, certification, and marketing of new wireless microphone devices, such as those that would include any technical changes that we may adopt in this proceeding. What considerations or factors affect these timeframes? Similarly, the Commission seeks comment on the life-cycles and/or replacement cycles associated with different wireless microphones. What are the general life cycles associated with different wireless microphones, including both high-end microphones and consumer devices? What types of factors, other than regulatory changes, necessitate replacement or otherwise affect or influence decisions by particular users to purchase new equipment? Given that different users are continually replacing equipment, what steps should the Commission or manufacturers be taking now and in the future to help address wireless microphone users' needs over the long term?

Operations in Other Countries

29. The Commission invites comment on whether the regulatory schemes for wireless microphone operations in other countries should inform our approach in this proceeding. Are there other regulatory models that are particularly effective? Would any of those models be appropriate for particular bands as we consider revisions to our rules?

Promoting Technological Advances

30. As the Commission seeks to accommodate the needs of wireless microphone operators, it also seeks to leverage technological advances that can help ensure that these needs can be met effectively, and in a manner that promotes the efficient use of spectrum. The Commission explores here the kinds of technological advances that achieve these goals.

Advances in Wireless Microphone Radio Technologies

31. *Advances in analog and digital transmission.* The Commission has already sought comment on the extent to which wireless microphone users today use analog or digital devices. Most users in the TV bands currently use analog devices, though digital devices increasingly are being developed and sold for operations in the TV bands. In other bands, devices today may be only analog or digital, or both. The Commission seeks to develop a full record here regarding technological developments in the basic design of wireless microphones that can enable more efficient wireless microphone operations, whether analog or digital, and promoting their uses in various spectrum bands.

32. The Commission begins by asking for comment on the state of analog and digital wireless microphone technologies that are available for use today. It asks that commenters address the state of technologies available in the different bands. Are there improvements in analog technologies that are enabling more efficient uses for various wireless microphone applications? What are they, and what additional efficiency gains are foreseen? What about for digital technologies? The Commission asks that commenters provide detailed information about the kinds of improvements in digital technologies that are being made with respect to microphone's performance capabilities for different types of uses.

33. In those bands in which both analog and digital devices operate, to what extent can the use of analog devices or digital devices, or some combination of the two, affect whether the spectrum is being used most efficiently to serve wireless microphone users' needs? While the Commission recognizes, that analog devices may be appropriate or necessary at this time for certain types of applications, digital devices can be effective for others, and we seek comment on the range of efficiency gains that may be possible depending on whether analog or digital devices, or a mix of the two, are used.

34. In particular, the Commission requests that commenters provide information on the state of analog and digital technologies that operate in the TV bands, and the extent to which operators are using the most efficient microphones that can serve their particular needs. In earlier proceedings, the Commission has noted that the number of analog wireless microphones

operating on a six-megahertz television channel may be as few as 6–8 microphones. More recently, manufacturers have developed microphones that operate more efficiently, including analog microphones that may allow twice that number on a six megahertz channel. The Commission asks that commenters provide information technological advancements that enable more efficient analog use. To what extent does the number of wireless microphones that can be deployed on a channel number depend on the power levels used, other operational factors, or the specific application(s) for which the wireless microphone is being used? Similarly, how many digital devices can operate on a television channel, and what operational factors or use factors might affect this number?

35. The Commission also invites comment on analog and digital devices in other bands, and the numbers of wireless microphones that can be accommodated by use of those particular technologies. In bands where analog devices are being used, are they necessary in these bands or can digital devices be used instead? What steps can manufacturers take to make analog and digital devices more efficient, if any? How much more efficient could these devices be, and how many more microphones might be able to operate on the same amount of spectrum, and for what types of uses? Do manufacturers have plans to take such steps, and if not, why not?

36. The Commission requests that commenters fully address the benefits and tradeoffs associated with use of analog and digital technologies. In earlier proceedings on the TV bands, wireless microphone manufacturers have indicated that analog devices may be necessary for certain types of uses (e.g., those with need for high quality audio, with lower latency). The Commission seeks to develop a full record on this issue, and seek comment on the extent to which this may continue to be the case. For what types of applications are analog devices necessary or appropriate? For what types of operations are digital devices well suited? To what extent are improvements in digital technologies (e.g., reductions in latency, improvements in fidelity) enabling more wireless microphone applications to be effectively served through digital technologies?

37. Are there rule changes that the Commission can adopt generally, or with respect to operations in particular bands, that would help promote more efficient use of spectrum by wireless microphone operations, whether analog or digital? For instance, are there technological standards for wireless microphone devices that should be adopted, such as the European Telecommunications Standards Institute (ETSI) standards for analog and digital emission masks, that would help promote more efficient use? Should such standards apply to particular operations in particular bands, or be adopted more generally across bands? As more efficient standards are developed, what actions should the Commission take to ensure that these standards are utilized by wireless microphone manufacturers in the future or that our rules are updated where necessary or appropriate?

38. To the extent more efficient analog or digital devices can effectively serve the needs of particular users, the Commission seeks comment on how best to encourage wireless microphone users to employ these more efficient technologies. Is the transition to more efficient devices already occurring? Have users been migrating to the use of more efficient wireless microphones, and if so how and why? Are manufacturers and distributors taking steps to promote the transition to use of more efficient wireless microphones in cases in which those microphones would be effective in meeting the needs of the particular users? What role should manufacturers and distributors play in this respect?

39. Considering that use of more efficient wireless microphones is an important component of accommodating wireless microphone users' needs in the future, what actions should the Commission take to encourage or promote the use of more efficient technologies? Should it require the use of digital technologies for certain types of uses, and if so, by what mechanisms would we accomplish that? Should we phase out the certification or sale of inefficient wireless microphone technologies, and if so, how would we define ''inefficient,'' and in what bands and on what timetable?

40. *Use of general purpose wireless standards.* The past several decades have seen widespread development and deployment of ''general purpose'' wireless technology standards that may be used for a wide variety of end-user applications. For example, the 802.11 family of standards serves as the basis of Wi-Fi technologies in the 2.4, 5 GHz bands, and other bands; the DECT standard provides for digital audio transmission in the 1920–1930 MHz band; and the LTE standard serves, increasingly, as a basis for broadband transmissions in several different licensed spectrum bands. The Commission inquires about the extent to which these, and other, general purpose technologies are now, or will be in the future, suitable for use in the wireless microphone context. The Commission is specifically interested to understand what kinds of use cases are appropriate for general-purpose wireless technologies and which are not. To what extent do general purpose technologies increase the ability of wireless microphones to share spectrum with other kinds of applications (e.g., in the Wi-Fi bands, discussed in Section III.C., of the NPRM), thereby potentially increasing the quantity of spectrum available for wireless microphones? Could the use of such technologies potentially improve performance and reduce cost of wireless microphone equipment? Should the Commission endeavor to promote the use of general purpose wireless technologies by wireless microphone users? What are the tradeoffs?

Other Technological Advancements

41. The Commission seeks comment on other technological developments that could promote more opportunities for accommodating wireless microphone operations in different bands over the longer term. Developments in these areas are not mutually exclusive.

42. *Equipment with replaceable components.* The Commission seeks comment on the development of replaceable components (e.g., modules) for the transmitters and receivers in the wireless microphone systems that operate on specific frequencies and can be exchanged with different components that operate on other frequencies available for wireless microphone operations. The use of such components potentially could reduce the costs to consumers to the extent changes need to be made in the way they operate their microphones in the future, *e.g.* in the event that the certain frequencies are no longer available to them, or if they update their equipment to newer, more efficient devices that may be capable of dynamically using the spectrum. Do wireless microphones today incorporate modular radio components? Do manufacturers contemplate including this kind of modularity in future models? To what extent would such components mitigate the costs of replacing wireless microphones that may no longer be permitted on certain frequencies? To what extent do they add new costs? If manufacturers are not including these component features, why not? Are there performance tradeoffs associated with

respect to including such components? What steps, if any, should the Commission take to promote the use of such microphones in certain bands, such as the TV bands?

43. *Tunability of Equipment within Bands.* The Commission ask for comment on the extent to which equipment is designed to be tunable within a band. Which types of microphones are tunable for which types of users? Are tunable microphones marketed only to more sophisticated users? What costs are associated with designing a tunable wireless microphone system? Do manufacturers anticipate developing more tunable microphones in the future? The Commission requests that commenters explain their considerations when determining whether or not to design tunable microphones.

44. *Multi-Band Equipment.* The Commission invites comment on the extent to which manufacturers are, or in the future will be, developing wireless microphones that can operate in more than one spectrum band. What kinds of technical or other issues are raised, and to what extent would these issues vary to the bands may not be adjacent or nearby? For instance, to what extent might this raise design issues (e.g., antenna, battery, or other component issues)? Could these devices help ensure that users have devices that can meet their needs when operating at locations where the availability of spectrum in different bands may vary? Could development of such devices promote economies of scale? Could they help ensure that users purchasing such devices would be more assured of having access to the spectrum resources they need? If there were multi-band devices, could this allow greater reliability that the microphones could address users' needs depending on the particular locations where those wireless microphones were needed? What are the tradeoffs with regard to developing such devices?

45. *Use of databases.* Wireless microphone technologies today do not use a database as a mechanism for indicating to the wireless microphone user that particular frequencies in a particular area were available, such as at particular locations that were not being used by other users with priority over the wireless microphone users. White space devices operating in the TV bands must access a database to determine that spectrum is available for their operations and that they would not potentially be interfering with other users at specified locations and times. Would wireless microphone systems potentially benefit from the ability to access to a database? Could requiring use of a database for gaining access to spectrum in a particular band or identifying particular locations and times where they may operate without causing interference to other users in the band help to mitigate or eliminate the concerns of other users in the band that wireless microphone operations might cause harmful interference to these other users? What might be the costs and benefits of developing and using a database, and would these differ depending on the needs of particular types of wireless microphone users?

46. *Electronic key or similar mechanisms.* Are there particular technologies, such as an ''electronic key'' or similar mechanism, that would ensure that a wireless microphone device be able to access and operate only on particular frequencies at particular locations and times, but nowhere else, thus eliminating the potential for harmful interference to other users (such as other users with primary or superior spectrum rights are particularly sensitive to harmful interference) and by so doing provide additional opportunities for wireless microphone operations in bands? Are there other approaches that would effectively limit wireless microphone operation to particular locations, thus protecting other operators from harmful interference? The Commission seeks broad comment on the development and use of these types of mechanisms and the tradeoffs or practicalities associated with them. Are there particular scenarios or bands in which use of these mechanisms could provide additional opportunities to access spectrum?

47. *Use of other technologies that promote opportunities to access additional spectrum.* The Commission seeks comment on other technological advancements that could promote greater opportunities for wireless microphones to share use of spectrum in different bands. Are there technological advances that are currently available or contemplated that better enable wireless microphones to adjust dynamically to a particular interference environment, either automatically or through coordination, to promote more efficient use among the wireless microphones or among wireless microphones and other users in the band? For instance, could devices that include sophisticated dynamic power variability capabilities help promote more intensive use of the spectrum resource in a given area? Would these more dynamic capabilities enable wireless microphones to vary or adjust power levels to minimize or eliminate interference to other users in a particular setting, or facilitate more re-use of the available spectrum? The Commission invites comment on whether technological advances along these lines could both facilitate more efficient use of the spectrum while also helping to ensure that they do not cause harmful interference to other users of the spectrum. Are there technologies that could enable certain wireless microphone applications to operate on spectrum licensed to wireless providers, subject to agreements reached with such providers? Are there other technological advancements that could help accommodate the various different wireless microphone users' needs over the longer term? What are they? Are there actions the Commission should take to promote these developments so that they occur in a timely fashion?

Operations in Specific Bands

48. In this section, the Commission examines opportunities for wireless microphone operations in different spectrum bands—both those in which wireless microphones currently are authorized to operate and other bands that may hold potential for accommodating wireless microphone uses, whether in the near or longer term.

VHF/UHF Television Bands

49. As set forth in the *Incentive Auction R&O,* the current VHF/UHF television bands (channels 2–51, except channel 37) will be reorganized following the upcoming incentive auction. As a result of this auction, the amount of spectrum allocated for television services will be reduced and repacked, some of the current TV bands spectrum will be designated for 600 MHz Band guard bands (including the duplex gap), and other TV bands spectrum will be repurposed for 600 MHz Band wireless services. These revisions will affect wireless microphone operations, which currently operate throughout in existing TV bands, in several ways. The Commission seeks comment on wireless microphone operations with respect to each of these bands—the TV bands, the 600 MHz Band guard bands, and the 600 MHz Band being repurposed for wireless services.

Discussion

50. In this section, the Commission seeks comment on Part 74 rule revisions that we can make to accommodate licensed wireless microphone (and other LPAS) operations in the VHF and UHF spectrum in the repacked TV bands that will continue to be available for TV broadcast services following the incentive auction. We also invite comment on how best to facilitate the

smooth transition of wireless microphones out of the repurposed 600 MHz Band following the incentive auction.

51. In this proceeding, the Commission does not address certain issues relating to wireless microphone operations in the TV bands and in the repurposed 600 MHz Band since these matters will be addressed instead in the part 15 proceeding. In particular, we do not here address the rules for unlicensed wireless microphone operations in the TV bands and the repurposed 600 MHz Band, which will be addressed as part of the part 15 proceeding. Similarly, the Commission does not address in this proceeding, the technical rules for operations of unlicensed wireless microphones in the guard bands, including the duplex gap. Nor does it address here the technical rules for licensed wireless microphone operations in the duplex gap, since the technical issues relating to their operations are intertwined with the technical issues concerning unlicensed operations in the duplex gap and protection of licensed operations outside of the duplex gap. Finally, the Commission will address revisions pertaining to the white spaces databases in our part 15 proceeding.

TV Bands

52. In this proceeding, the Commission invited comments on potential revisions to the existing rules for part 74 wireless microphones (and other LPAS) operations in the spectrum that will remain allocated for TV services following the repacking process. Specifically, it invites comment on revisions to the technical rules for LPAS operations on the VHF band; on permitting licensed LPAS operations on channels in locations closer to the television stations (including within the DTV contour), without the need for coordination, provided that the television signal falls below specified technical thresholds; on adoption of the ETSI emission mask standard for analog and digital wireless microphones; and general comment on other potential revisions concerning licensed LPAS operations in the TV bands.

VHF Band Revisions

53. *Background.* Under the existing technical rules for LPAS operations under part 74, licensed wireless microphone users that operate on a secondary basis in the VHF band (channels 2–13) operate generally under the same technical rules as for operations in the UHF bands. However, with respect to power levels, VHF band operations are restricted to no more than 50 mW, well below the 250 mW levels permitted for operations in the UHF bands. The Commission notes that several manufacturers have developed wireless microphones that make use this VHF spectrum. Our understanding, however, is that licensees make only limited use of this band for wireless microphone operations due to the limited power levels permitted.

54. *Discussion.* The Commission seeks comment on the current uses of the VHF television channels for wireless microphone operations, and the potential for expanding use of this spectrum for wireless microphone operations in the future. Are there technical impediments to making greater use of this spectrum for wireless microphones?

55. In particular, the Commission invites comment on whether it should revise the power limits for LPAS operations in the VHF band to conform to those applicable for LPAS devices in the UHF television band? What would be the benefits or risks associated with making such revisions? Due to the propagation characteristics of this band, would allowing higher power limits raise concerns regarding potential interference to TV stations operating in the VHF bands or the wireless video assist devices that operate in the upper VHF band? Would the minimum co-channel separation distance of 4 kilometer from the contour need to be increased? If so, to what distance? Or could a tiered requirement be implemented, such as where wireless microphones operating at 50 mW or less could comply with the 4 kilometer separation distance, while higher power operations would have to comply with a greater separation distance? The Commission asks that commenters explain fully the benefits or risks, including the kinds of wireless microphone operations that would be facilitated by such changes.

56. The Commission also invites comment on any other rule revisions concerning use of the VHF television spectrum that would facilitate more use of this spectrum for wireless microphone operations. It asks that commenters provide specifics about any proposals, and address the benefits and risks associated with such changes.

Licensed Co-Channel Operations Closer Than Specified Separation Distances

57. In this proceeding, the Commission seeks to develop a more extensive record on whether it should permit licensed wireless microphone operations on a co-channel basis closer than the generally applicable separation distances set forth in our rules, without the need for coordination, provided that certain specified conditions at the locations where the wireless microphone operations would take place. Our goal is to provide more opportunities for licensed wireless microphone operations in the spectrum that will continue to be allocated for television services where the wireless microphone operations would not cause harmful interference to TV operations. Permitting such operations could help ensure that licensed operators have access to more channels, particularly in indoor locations.

58. The Commission proposes to allow LPAS licensees to operate co-channel with television closer to the television station than provided by the separation distance rules, including inside the DTV contour, in those locations in which the co-channel TV signal is below a specified threshold, which would indicate that the over-the-air TV signal unlikely to be received or receivable. Provided that an appropriate TV signal threshold were established, we believe that such a rule serve to ensure that wireless microphone operations could have access to additional channels in the TV bands spectrum without causing harmful interference to any over-the-air television viewers at those particular locations.

59. If the Commission takes this approach, what would the suitable TV signal threshold be? One commenter in the incentive auction proceeding proposed that the suitable threshold would be −80 dBm over 200 kHz. The Commission seeks comment on this threshold, or any other suitable threshold. It asks that commenters provide technical analyses of the threshold that they propose that we adopt.

60. In addition, the Commission requests comment on whether, apart from establishing such a TV signal threshold, it should adopt any other safeguards to ensure that licensed wireless microphone operators comply with this threshold and do not otherwise cause harmful interference to TV reception. The Commission notes at the outset that because we would limit these types of operations to licensed wireless microphone users, we would expect such users to have the requisite wireless microphone systems, as well as technical and operational abilities, to be able to determine the level of the co-channel TV signals at a given location, and thus would be able to comply with any threshold rule that we adopted. Is this a reasonable expectation? To what extent would a wireless microphone operation require a low TV signal to be

able operate effectively on a co-channel basis? Should we require licensed wireless microphone users to register their co-channel operations in the TV bands databases, which could provide information to any television licensee concerned about possible harmful interference? Are there other actions we should take?

61. As an alternative approach, the Commission seeks comment on whether it should permit co-channel licensed wireless microphone operations in indoor venues, such as in theaters or music auditoriums. Could an appropriate approach towards indoor operations be developed that would also effectively preclude harmful interference to any potential TV viewers at indoor locations? For instance, could certain locations be readily identified where wireless microphone operations can be permitted, provided of course that they are operated consistent with applicable technical requirements, including power limits and out-of-bound emissions requirements? Or, considering that in order to operate effectively wireless microphones need access to channels that are sufficiently interference-free, is it reasonable to expect that co-channel wireless microphone operations would only take place in indoor locations on channels with relatively low or effectively non-existent TV signal, and thus conclude that such operations would not be likely to effectively harm TV viewers? Some commenters in the incentive auction proceeding suggested that such operations may already take place without incident. As the Commission explores this approach, it seeks comment on the benefits or downsides of allowing licensed wireless microphone operations at indoor locations, or at specified types of indoor locations. The Commission asks that commenters provide any technical analysis bases for their recommendations.

62. The Commission also invites comment on other approaches that it should take on expanding wireless microphone operations on a co-channel basis closer to television station operations. Again, commenters proposing any alternative approaches should provide technical analyses to support their approaches, and discuss the benefits of such an approach and how their approaches would not cause harmful interference to channels that would be used for wireless microphone operations.

Adoption of ETSI Emission Mask Standards for Analog and Digital Wireless Microphones

63. To promote more efficient use of the available channels in the spectrum in the TV bands spectrum, the Commission proposes revising the emission masks applicable to wireless microphones and LPAS devices, both with respect to analog and digital wireless microphones, to comply with the applicable ETSI standards for analog and digital wireless microphones that operate over 200 kHz channels. Specifically, the Commission proposes to require that emissions from analog and digital unlicensed wireless microphones comply with the emission masks in Section 8.3 of ETSI EN 300 422–1, *Electromagnetic compatibility and Radio spectrum Matters (ERM); Wireless microphones in the 25 MHz to 3 GHz frequency range; Part 1: Technical characteristics and methods of measurement.* The Commission believes that requiring wireless microphones to meet these tighter emission requirements will protect authorized services in adjacent bands from harmful interference, and will improve spectrum sharing by wireless microphones. We seek comment on this proposal.

64. In particular, the Commission seeks comment on the benefits of requiring unlicensed wireless microphones to comply with the ETSI limits, and whether these benefits would outweigh the costs. To what extent would adoption of the standards improve the efficiency of wireless microphone operations? If so, in what ways? To what extent would more microphones, whether analog or digital, be able to make use of the TV bands spectrum? Are these limits necessary to protect authorized services in adjacent frequency bands? To what extent would compliance with the proposed limits improve spectrum sharing by wireless microphones? To what extent have wireless microphone manufacturers developed wireless microphones that already comply with these standards? Would equipment manufacturers have difficulty in complying with these limits? Would a requirement to meet the ETSI standard affect the cost of a wireless microphone system?

65. The Commission also seeks comment on whether we should specify separate emission masks for analog and digital microphones, or whether a single mask is sufficient. For example, ETSI EN 300 422–1 suggests that its mask for digital microphones could also be used for analog microphones. If we were to decide to adopt these standards, how quickly should we require new devices to comply with the new standards? Because the ETSI emission masks are defined only over a frequency range of plus or minus one megahertz from the wireless microphone carrier frequency, we seek comment on the emission limits that should apply outside of this frequency range. For example, should this limit be the same as the emission limits at the outer edges of the ETSI masks (-90 dBc)? Is some other limit more appropriate?

66. In addition to the ETSI standards, or as an alternative, are there other technical standards that the Commission should adopt to promote more efficient use of the spectrum available for wireless microphone operations in the TV bands? If so, the Commission asks that commenters explain the bases for adoption of these standards, along with the associated benefits or potential costs. How quickly should the Commission require that wireless microphones comply with such standards?

Other TV Bands Revisions

67. The Commission also seeks comment generally on whether the Commission should adopt any other rule revisions for operations of wireless microphones in the TV bands spectrum that would facilitate more effective and efficient operations in these bands in a manner that would be consistent with the secondary status of LPAS operations in the band. To the extent that commenters contend that other rule revisions would be appropriate, the Commission asks that commenters provide detailed information on reasons for the proposed changes and the types of specific rules that they advocate.

Eligibility for Licensed Operations in the Duplex Gap

68. In the *Incentive Auction R&O,* the Commission provided that broadcasters and cable programming networks using wireless microphones on a licensed basis would be able to obtain interference protection from unlicensed devices in a portion of the duplex gap at specified times and locations, on an as-needed basis. The Commission is addressing the technical issues concerning licensed wireless microphone operations in the duplex gap in the companion part 15 proceeding.

69. The Commission seeks comment on whether it should expand eligibility for licensed wireless microphone operations in the duplex gap to include all of the entities eligible for part 74 LPAS licenses in the TV bands. Would expanding eligibility to those entities

eligible for part 74 LPAS licenses in the TV bands create problems for broadcasters or cable programming networks operating on this spectrum, or would these different users for the most part operate at different locations, such that their operations would not likely interfere with each other?

Transition Out of the 600 MHz Band Repurposed for Wireless Services

70. The Commission seeks comment on how best to facilitate a smooth transition as wireless microphone and other LPAS users cease their operations on the repurposed 600 MHz Band frequencies no later than the end of the post-auction transition period (i.e., 39 months after the issuance of the *Channel Reassignment PN*). Achieving a smooth transition will involve actions by the Commission, by manufacturers and distributors of wireless microphones, and by the various wireless microphone operators themselves, both licensed and unlicensed users. Although the specific UHF band frequencies that will be repurposed for 600 MHz Band wireless services will not be known until following the incentive auction, beginning preparation for transition as soon as possible will contribute to a smoother transition.

71. The Commission also seeks comment on steps it should take to facilitate a smooth transition in which wireless microphone operations vacate the repurposed spectrum in the 600 MHz Band. The Commission asks for comment on the extent to which consumer education and outreach can help to achieve this goal, and the means by which information can be made available to wireless microphone users in order to inform them of the need to vacate the band. The Commission also requests that commenters address whether labeling requirements, such as point of sale disclosure, can help to facilitate the transition. In addition, it proposes revising our rules to prohibit certification of part 74 wireless microphones that operate in repurposed 600 MHz Band spectrum beginning nine months after the release of the *Channel Reassignment PN,* and to prohibit the manufacture, import, sale, offer for sale, or shipment of such wireless microphones in the 600 MHz band in the United States, 18 months after the release of the *Channel Reassignment PN.* Finally, we propose to modify by rule LPAS licenses with frequencies that will be in the repurposed 600 MHz band and to delete these frequencies from LPAS licenses because they will not be available for such use after the end of the transition.

72. In addition to the specific issues the Commission raise, comments should discuss how particular steps will promote ready access to the repurposed spectrum by 600 MHz Band wireless licensees, while at the same time providing for an orderly transition process for secondary and unlicensed users that currently are serving various important consumer needs using this spectrum.

Consumer Education and Outreach; Disclosure Requirements

73. The Commission seeks comment on how to inform users of wireless microphones on the steps necessary to prevent interference to new wireless operations in the 600 MHz spectrum, consistent with the Commission's goals expressed in the *Incentive Auction R&O.* The Commission anticipates that there will be a need for significant education and outreach directed at wireless microphone users that must commence well before the auction and continue for a number of years beyond the end of the 39-month transition period. These education and outreach efforts must be undertaken by the Commission, manufacturers, wireless microphone users groups, and relevant trade publications and other possible sources of information for wireless microphone users. As a companion to these efforts to educate consumer awareness on developments concerning the operation of wireless microphones, the Commission also proposes requiring that written disclosures accompany new devices at the point of sale to provide further education to wireless microphone users on the devices' operations.

74. *Consumer Education and Outreach.* The commission seeks comment on the consumer education and outreach efforts that should be employed to educate wireless microphone users, particularly unlicensed users operating in the repurposed 600 MHz band. Our goals are to make information available so users are aware that they must cease operating their wireless microphones on the repurposed 600 MHz Band no later than the end of the transition period (*i.e.,* 39 months after the release of the *Channel Reassignment PN*); to set in motion a process so they are aware of relevant factors concerning the operation of wireless microphones that are currently in use; and to establish a means for users to locate additional spectrum and equipment for their operations. A successful consumer education and outreach campaign will involve the Commission staff working with a broad group of interested entities, including wireless microphone manufacturers, wireless microphones users, and user representatives.

75. Given that a portion of the UHF spectrum that is currently used and available for wireless microphone operations may no longer be available following the incentive auction, the Commission seeks comment on how wireless microphone users can be provided access to information on the specific frequencies and the geographic areas of repurposed spectrum that will no longer be available for wireless microphone use at the end of the transition. What specific information should be provided to wireless microphone users to ensure that they know the requirements for operating in the repurposed spectrum during the transition period and the need to exit the band by the end of the transition? Although the *Channel Reassignment PN* will provide information on the spectrum that will be repurposed and no longer available for wireless microphones, first the Commission seeks comment on what steps can be taken to provide wireless microphone users with information on the transition prior to the auction. For example, it seeks comment on whether explanations could be provided on the Commission's Web site and on the Web sites of manufacturers that would explain the steps required under the Commission's rules to vacate the repurposed 600 MHz Band, and any information on alternative spectrum that is currently available outside of this spectrum, as well any additional spectrum bands that may become available for wireless microphone operations beyond those already provided for in the rules.

76. What other means should be employed to provide wireless microphone users notice of the repurposed spectrum that will be assigned to new wireless licensees, including the specific frequencies in the UHF spectrum and the geographic locations that will no longer be available for wireless microphone operations? The Commission seeks comment on whether it would it be beneficial for wireless microphone users to have access to a database that identifies spectrum in the repurposed 600 MHz Band. For example, should some form of online mapping tool be made available to allow users to enter the location and operating frequencies of a wireless microphone and determine whether it operates in the repurposed 600 MHz Band? In the event that a database or similar approach is adopted, the Commission seeks comment on who should be responsible for developing and maintaining (hosting) it, including

who should be responsible for its cost. Commenters should provide quantitative and qualitative data on costs and benefits of their proposals.

77. Further, should the Commission work with wireless microphone manufacturers to obtain information on models of wireless microphones that the Commission could list on its Web site? For example, this information could include a list of all models of wireless microphones sold in the U.S., and all wireless microphone models that operate in the repurposed 600 MHz Band, as well as where on the device or in its product literature the user could look to determine the frequencies on which it is capable of operating. The Commission seeks comment on whether making this type of information publically available would help to facilitate a smooth transition from the 600 MHz Band. It also seeks comment on the costs and benefits of this approach, as well as alternative approaches.

78. In addition to steps that may involve manufacturers, the Commission seeks comment on what steps other parties associated with the sale and operation of wireless microphones may be able to take to provide users with information relevant to the transition. These other parties may include: Wireless microphone distributors and retailers; parties that lease or manage wireless microphones; trade associations and user groups, including those that have participated in Commission proceedings concerning wireless microphones; organizations that host Web sites and publish information that addresses wireless microphone operations and use or are reasonably expected to have significant numbers of wireless microphone users among their members and readers; and engineering and industry associations or other groups with members that use or operate wireless microphones. Involvement in education and outreach by these parties will be essential, given users' investment in wireless microphone equipment and the upcoming changes regarding wireless microphone use, including the requirement that they vacate the 600 MHz Band. Further, it is important that education and outreach extend to information concerning any newly-allocated spectrum for wireless microphone operations and the potential for users to opt for a suite of wireless microphones operating in different spectrum bands and with different capabilities, depending on the user's specific requirements. The Commission notes that wireless microphone users can encompass a wide range of entities, including both licensed and unlicensed users, and parties with differing levels of wireless microphone needs and expertise covering many different applications. Based on these considerations, it is likely that the need for information on the various spectrum bands that will be available for wireless microphone operations, and the conditions specific to each, will be vital. The Commission seeks comment on these matters, and on what steps can be taken to assure that the information to educate users on the transition will be commensurate with the appropriate needs and levels of expertise of all users.

79. The Commission seeks comment on what additional information it should make available for wireless microphone users, including Commission-issued consumer ''fact sheets'' and ''frequently asked questions'' (FAQ's) which would address, among other matters, information on operation in the 600 MHz Band, the reason for the need to operate on frequencies outside of that band following the transition, the availability of other frequency bands for wireless microphone use, and the need to comply with Commission rules. The Commission further seeks comment on how to release or distribute these materials in order to most effectively and efficiently reach the target audience of wireless microphone users.

80. The Commission seeks comment on the specific actions that wireless microphone manufacturers, distributors, retailers and other entities comprising the wireless microphone community should take to inform the wide range of wireless microphone users about the ongoing developments concerning wireless microphone use—particularly the need to vacate the repurposed 600 MHz Band, the timetable for doing so, and the conditions for operating in the band during the transition period. The Commission seeks comment on whether and to what extent these entities can make this type of information available, including, as appropriate, by posting it on their Web sites, including it in all sales literature, or taking other steps to inform current or potential wireless microphone users of matters concerning the operation of their devices. The Commission also seeks comment on whether manufacturers would consider rebates, equipment trade-ins, or similar programs to facilitate the transition, and what effect the 39-month transition period would have on a decision to implement such a program. In addition, we seek comment on the economic costs and benefits of adopting consumer outreach measures.

81. *Disclosure Requirements.* The Commission proposes to revise its point-of-sale disclosure requirement that the Commission adopted in the *Wireless Microphone Report and Order* in order to provide information to wireless microphone users that may have to purchase or lease new equipment so that they can vacate the repurposed 600 MHz Band. In the *TV Bands Wireless Microphones Report and Order,* the Commission adopted a point-of-sale requirement to help assure that consumers were informed of their rights and obligations if they chose to operate wireless microphones and other low power auxiliary stations in the core TV bands (defined in the rule as channels 2–51, excluding channel 37). Specifically, the Commission adopted a requirement for manufacturers and distributors of wireless microphones that operate in the core TV bands to provide a written disclosure informing consumers of the requirements for operating devices in that spectrum and to display the disclosure at the point of sale and on their Web sites. The Commission also provided that persons who manufacture or market wireless microphones destined for export and capable of operating in the 700 MHz Band must include labeling stating that the devices cannot be used in the United States.

82. The Commission proposes to revise the existing point-of-sale disclosure requirement in order to facilitate a smoother transition in which wireless microphone users are informed of the need to vacate the repurposed 600 MHz Band, while fully understanding their rights and obligations during the transition period and at the end of the transition period. With regard to sales of wireless microphones that are capable of operating in repurposed spectrum, it proposes to require that such sales include point-of-sale disclosures that inform buyers that they are buying a microphone that cannot be used in certain frequencies following the transition. The Commission also seeks comment on how point-of-sale disclosures could be designed to effectively address any ban on manufacturing and marketing of wireless microphones that are capable of operating in the repurposed 600 MHz Band. The Commission proposes that the revised point-of-sale disclosures should direct buyers to the manufacturer's toll free telephone number or the manufacturer's Web site where the buyer can obtain more detailed information on the extent to which the microphone may be affected by repurposing the600 MHz Band.

Should it retain the existing language in the point-of-sale disclosure requirement that includes the Commission's toll free number and the Commission's Web site where users can obtain additional information on the operation of wireless microphones during the transition period and after the transition period? What other information should be included in the disclosure?

83. The Commission proposes that the effective date for any disclosure requirement, including a point-of-sale requirement, which it may adopt in connection with this or a related proceeding, shall be 18 months after the release of the *Channel Reassignment PN*—which will mark the effective date of channel reassignments based on the repacking process, specify any specific channel assignments for television stations that will continue to broadcast, and start the clock running on the post-auction transition period—or should some other date be used instead? The Commission seeks comment on the particular factors that should enter into this determination. It notes that in adopting the current disclosure requirement, the Commission stated that it would remain in effect until the effective date of the final rules adopted in response to the 2010 *TV Bands Wireless Microphones FNPRM.*

Post-Auction Prohibition of the Certification, Manufacture, or Marketing of LPAS Devices Operating on the 600 MHz Band

84. All wireless microphones that now operate in the TV bands are certified as compliant with Part 74, Subpart H of the Commission's rules. The Commission decided in the *Incentive Auction R&O* that all wireless microphones that operate in the portion of the TV bands that will be repurposed for licensed wireless services may continue to operate in that spectrum during the post-auction transition period but must cease those operations no later than 39 months after release of the *Channel Reassignment PN.* At the end of the post-auction transition, licensed microphones will be permitted to operate in a portion of the duplex gap, and unlicensed wireless microphones will be permitted to operate in the guard bands and duplex gap.

85. Because of these future changes in the permitted operating frequency range for wireless microphones, plus the rule changes for these devices that we propose in the *NPRM* and in the *Part 15 NPRM,* the Commission need to establish cutoff dates for the certification, manufacturing, and marketing of wireless microphones in the repurposed spectrum to ensure that manufacturers cease making and marketing equipment that cannot be legally used after a certain date. Cutoff dates will encourage manufacturers to concentrate on developing wireless microphones that operate in compliance with new part 74 and part 15 rules. Because similar technical requirements would apply to both licensed and unlicensed wireless microphones, the Commission proposes to apply to both the same transition rules for certification, manufacturing, and marketing. This approach would be the least disruptive to wireless microphone manufacturers and users. The *NPRM* addresses these issues for licensed wireless microphones, and the *Part 15 NPRM* addresses these issues for unlicensed wireless microphones.

86. Because wireless microphones will no longer be authorized to operate in the 600 MHz Band beyond 39 months after the release of the *Channel Reassignment PN,* the Commission proposes revising its rules to prohibit the certification, manufacture, import, sale, lease, offer for sale or lease, or shipment (collectively, ''manufacture or marketing'') of wireless microphones devices intended for use in the repurposed 600 MHz Band in the United States. The Commission proposes taking this action pursuant to its authority under section 302(a) of the Communications Act.

87. The Commission proposes this prohibition to ensure that wireless microphones will vacate the 600 MHz spectrum by the end of the transition. This action would be consistent with Commission actions when it required wireless microphones to cease operating in the former TV bands that were repurposed for 700 MHz Band wireless services and prohibited the manufacturer and marketing of wireless microphones intended for use in the 700 MHz Band. The Commission is concerned that without this prohibition there may be greater potential for unauthorized use in the repurposed 600 MHz Band, given the difficulty in educating users about the scope of the devices' operations and problems we may otherwise encounter in enforcing a requirement that all wireless microphones users leave the band by the end of the transition. The Commission seeks comment on this proposal. It notes, however, that some frequencies may not be cleared nationwide as a result of the incentive auction, creating some impaired blocks in the 600 MHz Band. The Commission proposes that parties may no longer submit applications to certify part 74 wireless microphones that operate in repurposed TV spectrum beginning nine months after the release of the *Channel Reassignment PN.* It also proposes that we will not certify wireless microphones under part 74 that would operate in the 600 MHz guard bands or the unlicensed portion of the duplex gap. The Commission seeks comment on these proposals. In particular, it seeks comment on the appropriateness of the proposed cutoff dates. Should we provide longer or shorter time periods? Should we also require that, in any event, parties may not submit applications to certify wireless microphones that operate in repurposed TV spectrum later than 24 months after the effective date of the service rules we adopt in this proceeding, and microphones that do not comply with the new rules may not be manufactured and marketed later than 33 months after the effective date of the service rules the Commission adopts in this proceeding?

88. The Commission also proposes that the effective date of any prohibition on manufacturing or marketing these devices will be 18 months after the release of the *Channel Reassignment PN.* The Commission notes that the particular frequencies that will need to be vacated will not be known until the release of the *Channel Reassignment PN,* although parties have been on notice since at least 2012 that wireless microphones may have to transition out of portions of the 600 MHz Band. The Commission also seeks comment on the extent to which manufacturers and other entities have already begun to educate current and potential wireless microphone users about the potential for a transition out of the 600 MHz Band. In addition, the Commission seeks comment on the economic costs and benefits of different effective dates for the proposed prohibition on manufacturing or marketing.

89. Finally, to the extent that the Commission determines to prohibit such manufacture or marketing, we propose that any such ban would not apply to devices manufactured in the United States solely for export. It seeks comment on this proposal.

Modification of LPAS Licenses To Remove Authorization for Operations on the 600 MHz Band

90. Pursuant to our authority under Section 316 of the Communications Act, the Commission proposes to modify existing LPAS licenses, to the extent necessary, to delete frequencies identified as repurposed for the 600 MHz Band in the *Channel Reassignment PN,* effective on the date that the post-auction transition period ends. The Commission has already taken action in

the *TV Bands Wireless Microphones Second Report and Order* adopted earlier this year to ensure that any LPAS licenses granted between the effective date of that order and the end of the post-auction transition period would be subject to the condition that operation in the repurposed 600 MHz Band must cease by the end of the post-auction transition period.

91. The Commission's proposed actions in the instant proceeding would similarly modify, to the extent necessary, all other LPAS licenses granted prior to the effective date of *TV Bands Wireless Microphone Second Report and Order* that authorize operations on frequencies that will be repurposed for the 600 MHz Band. In addition, the Commission proposes that following these license modifications, the LPAS licenses will continue to include authorization to use all frequencies currently included in those licenses other than the repurposed 600 MHz Band. Finally, we propose that if a licensed user must cease operations of a wireless microphone prior to the end of the post-auction transition period (*i.e.,* because it causes harmful interference to any 600 MHz licensee's operations), the license relating to that wireless microphone will be modified automatically without Commission action to delete the authorization to operate on the repurposed 600 MHz Band, effective on the date that operations are required to cease.

92. The Commission seeks comment on these proposals, and on the extent to which their adoption would promote the public interest by facilitating the clearing of all licensed wireless microphone operations from the repurposed 600 MHz Band by the end of the transition period.

26.100–26.480 MHz, 161.625–161.775 MHz, 450–451 MHz, and 455–456 MHz Bands

93. The Commission seeks comment on the current use of these bands for wireless microphone operations, and the future for more expansive use of these bands. What particular types of wireless microphones are used in the bands, and for which types of applications are they best suited. Considering the small bandwidths available in each of these bands, what kinds of limitations are there on the types of applications that can be served using these bands? How many microphones can operate on these bands using today's technologies? Are there technological advances that may promote more intensive use? The Commission seeks comment on any potential revisions that it should make to facilitate the use of these bands for wireless microphone operations.

88–108 MHz FM Band

94. *Background.* Over the years there have been some wireless microphone operations in the 88–108 MHz FM band on an unlicensed basis. As discussed, wireless microphone operations on this spectrum was permitted before wireless microphones were authorized to access any channels in the TV bands. Wireless microphones that comply with the rules for unlicensed device operations in this band, as sets forth in § 5.239 of our part 15 rules, may operate on no more than a 200 kHz bandwidths with low emissions (field strength of emissions must not exceed 250 microvolts/meter at 3 meters).

95. *Discussion.* To what extent do wireless microphone users continue to make use of this band for their operations? If so, for what types of wireless microphone applications? To what extent will use of the spectrum in this band be useful for accommodating wireless microphone users' needs in the future? Are there any rule revisions that would facilitate use of this spectrum while also preserving these channels for use by the primary FM broadcast services? The Commission asks that commenters proposing any rule revisions submit technical information in support of their proposals, as well as analysis of the benefits of such revisions and likely impact on FM broadcasters.

169–172 MHz Band

96. *Background.* Under the Commission's part 90 rules, entities eligible to hold a Public Safety Pool or Industrial/Business Pool license may operate wireless microphones on a secondary basis on certain frequencies in the 169–172 MHz band, which is allocated primarily for federal use. Specifically, these rules permit wireless microphones to be operated on only eight frequencies: 169.445 MHz, 169.505 MHz, 170.245 MHz, 170.305 MHz, 171.045 MHz, 171.105 MHz, 171.845 MHz, and 171.905 MHz. The emission bandwidth may not exceed 54 kHz, the frequency stability of the microphones must limit the total emission to within ± 32.5 kHz of the assigned frequency, and operations may not exceed an output power level of 50 milliwatts. Entities eligible to operate wireless microphones under the part 90 rules include a variety of users, including those eligible to hold LPAS licenses under part 74 as well as many other entities, including: state and local government entities; commercial entities in general; educational, philanthropic or ecclesiastical institutions; clergy; hospitals; clinics; and medical associations.

97. Wireless microphone operations are not protected from other licensed operations in the band and must not cause interference to any government or non-government operations, and wireless microphone license applications are subject to government coordination. The federal systems in the band are required to be capable of narrowband operations on 12.5 kHz channels. The other non-federal licensed operations in the band, which also are secondary to the federal allocation in the band, operate on narrowband channels and include: (1) operations by licensees on 36 specified assignable channels, no larger than 11.25 kHz, between 169.425 MHz and 171.925 MHz, for the purpose of transmitting hydrological or meteorological data: (2) operations by licensees on 9 assignable channels, no larger than 11.25 kHz, between 170.425 MHz and 172.375 MHz, for forest firefighting and conservation purposes (four assignable east of the Mississippi River and five assignable west of the Mississippi River); and (3) operations assignable on one 11.25 kHz channel for public safety activities; and remote pickup broadcast stations on one 12.5 kHz channel at 170.15 MHz in certain parts of the country.

98. In the 2010 *TV Bands Wireless Microphones R&O and FNPRM,* the Commission sought comment on whether it should revise these part 90 rules to facilitate broader wireless microphone use in these frequencies. Some commenters in that proceeding suggested that operating in this band may offer additional opportunities for some licensed wireless microphone operations, though several indicated that wireless microphone operations under these rules may not currently provide a viable option for all wireless microphone users, particularly where ''premium professional audio quality'' is required. One comment also indicated that the few available frequencies were insufficient except for small users.

99. In this proceeding, the Commission requests information about the current use of spectrum in the 169–172 MHz band for wireless microphone operations, and it requests comment on the potential for more expansive and intensive use of this spectrum. In particular, the Commission ask for comments on different ways in which the spectrum in the band could be used for wireless microphone operations without interfering with the federal operations, and the other secondary services that may use portions of this band at particular locations. The

Commission also inquires about the technical rules that we should adopt were we to authorize additional wireless microphone use of this band.

100. Commenters should provide information about how this spectrum is currently used by wireless microphones and describe the specific uses and applications for such devices under part 90. In particular, the Commission asks that commenters address why relatively few entities are licensed to operate wireless microphones in this band. To what extent, for instance, does the relatively narrow bandwidth permitted under Part 90 (with 54 kHz emission mask limitation) affect the audio quality and the types of usage on those frequencies when compared with part 74 LPAS systems in the TV bands (permitting as much as 200 kHz)?

101. The Commission also seeks comment on whether and what steps it could take to make the existing frequencies a more viable option for more wireless microphone users. The applicable technical rules are over thirty years old, and the Commission seeks comment on the extent of subsequent technical improvements in wireless microphone technology in this band. The Commission also seeks comment on the technical specifications of current microphones in this band and what rule changes would be necessary to enable improved fidelity to support additional wireless microphone applications.

102. Commenters should also discuss the potential for future wireless microphone use in these frequencies, as well as how revisions could make this spectrum more useful for wireless microphone applications. Since the current channels available for microphones include four sets of channels that are close to each other, one possible action we might take would be to allow wireless microphone licensees to combine each of the neighboring sets of channels with each other, making four channels with larger bandwidth available for wireless microphone operations. For instance, the authorizations for operating on channels 169.445 MHz and 169.505 MHz could be combined, allowing for operations across the two channels over a bandwidth of approximately 120 kHz, with the center frequency being at 169.475 MHz. Would allowing these channels to be combined to this larger bandwidth accommodate additional wireless microphone uses, and do commenters support such action? Commenters also should discuss whether such a revision would increase the likelihood of interference to federal use or other secondary non-federal use of the spectrum, and whether the rules also should include additional provisions to protect these other users.

103. Another approach would be to make as much of the 169–172 MHz band as possible available for wireless microphone use on a secondary basis. Secondary operations are not normally coordinated with primary operations. Given the relatively low power of wireless microphones and the limited nature of their use we believe the risk to primary services is relatively small except perhaps in rare instances of operation in close proximity. Nevertheless, are there certain circumstances where coordination with the federal government or other incumbent services may be appropriate? What impact might this have on wireless microphone operations in the band, as well as on other operations in the band? Alternatively, should certain areas be excluded for licensed wireless microphones operating in this band? In considering this possible expansion of wireless microphone use across the band, the Commission notes that there are many locations, or many frequencies at particular locations, where the spectrum is not being used either by the federal government or by other secondary users. The Commission seeks comment on whether wireless microphone licensees should be allowed to operate on channels of bandwidths up to 200 kHz (if available at particular locations), the same as permitted in the TV bands, and in addition should be required to comply with the ETSI standards that we are proposing to adopt with respect to wireless microphone operations under the technical rules for LPAS device operations in the TV bands and other bands. The Commission seeks comment on this approach, and whether such an approach could be designed in such a way as to protect federal and other secondary operations from interference from wireless microphone operations. Under this approach, to what extent could certain types or locations of wireless microphone use (e.g., indoor uses) more easily be accommodated? If the Commission were to provide authorization for more expansive use by wireless microphones licensees, it seeks comment on the service rules that we should adopt. The Commission also seeks comment on the technical rules that should apply for wireless microphone operations. For instance, under this approach, to what extent should we adopt other technical requirements that would apply to LPAS devices that operation in the VHF TV bands that currently apply (including restricting power to 50 mW, the same as permitted wireless microphones currently in the 169–172 MHz band), or under our proposed revisions for operations in the TV VHF band (which would permit higher power levels, up to 250 mW)?

104. In addition, the Commission seeks comment on any other approaches it could take to facilitate wireless microphones operations in the 169–172 MHz band. Commenters proposing other approaches should provide the rationale for such approaches, including how those approaches could be designed to protect incumbent operations of other services in the band. To the extent that the Commission revises technical rules to provide more access to spectrum in these bands, it asks that manufacturers address how quickly new devices might be manufactured and made available in the marketplace. Are there other equipment issues that we should address?

944–952 MHz Band and Adjacent 941–944 MHz and 952–960 MHz Bands

105. Under current rules, broadcasters and broadcast network entities already are permitted to operate wireless microphones and other LPAS devices in 8 megahertz of spectrum in the 944–952 MHz band on a licensed basis. In this section, the Commission seeks comment generally on LPAS operations in the 944–952 MHz band, and it proposes to adopt the ETSI standards for analog and digital wireless microphone operations and to expand eligibility for licensed LPAS operations to include the same additional entities that currently are eligible to operate LPAS devices on a licensed basis in the TV bands. The Commission also proposes to permit LPAS operations on a licensed basis in portions of the two spectrum bands immediately adjacent to the 944–952 MHz band (941–944 MHz and 952–960 MHz bands), which potentially could enable licensed wireless microphone users access to up to nineteen megahertz of spectrum across the 941–960 MHz frequencies, depending of course on the availability of unused spectrum across these frequencies.

944–952 MHz Band

106. The Commission requests that commenters provide information about the current uses of this band for licensed wireless microphone operations, as well as the potential for more intensive use of this band for these operations among the other broadcast services that use the band. How extensively do LPAS licensees make use of this 8-megahertz band, and in what types of locations? How much spectrum is available for wireless microphone

uses in the band, considering that the other authorized services are point-to-point operations are at fixed locations? The Commission seeks comment on both outdoor and indoor uses. For what types of wireless microphone operations is that band used? What are the advantages and disadvantages of using this band for wireless microphone operations?

107. Similarly, the Commission requests comment on the potential for more intensive use of this band in the future. Considering that less spectrum may be available for wireless microphone operations in the UHF television bands, do licensees expect to make greater use of this band in this band, including migration particular types of uses to this spectrum when they are spectrum-constrained in the TV bands? If so, for what types of applications? Do the propagation features associated with this spectrum band, and its relatively close proximity to the UHF television band, facilitate particular types of wireless microphone applications? For instance, is this band particularly well-suited for high-quality uses? What are the potential limitations on the use of this band for licensed wireless microphone operations? Commenters should provide whatever information they believe may be helpful to the Commission as we evaluate the role that this band can play in helping accommodate the various needs of wireless microphone users over the near and long term.

108. In our discussion of licensed LPAS operations in the TV Bands, the Commission proposes to adopt the ETSI emission mask standards both for analog and digital microphones. Here, the Commission proposes adopting those standards for LPAS operations in the 944–952 MHz Band. The Commission seeks comment on this proposal.

109. In addition to seeking comment on use of this band by existing licensees, the Commission proposes expanding eligibility in the 944–952 MHz band to include additional classes of wireless microphone users, in particular all of the other entities eligible for operation of LPAS devices in the TV bands on a licensed basis, which have wireless microphone needs similar to those of broadcasters and broadcast network entities and merit license status in the TV bands. Considering that these other entities are sophisticated users, and often already coordinate their wireless microphone operations in the TV bands with broadcasters, the Commission believes that such users should be able to effectively work with broadcasters when accessing spectrum at different locations. Expanding eligibility for these uses potentially could help ensure that entities that merit licensee protection in the TV bands, and may have access to less TV bands spectrum following the incentive auction, have access to additional spectrum that they may need for their licensed operations. The Commission seeks comment on this proposal. Alternatively, should the Commission expand eligibility to include a subset of these other TV bands LPAS licensees, or some other group of entities? If so, for what reasons?

110. Are there technical limitations and other considerations we should weigh when assessing expansion of licensee eligibility in this band? Would expansion have the effect of limiting the spectrum at particular locations available for use by broadcasters? Alternatively, would the likely operations of these LPAS wireless microphones by different users at different locations help ensure that the low power, short-range operations would not overlap or cause interference among LPAS operations? Considering the technical characteristics of the fixed Aural Broadcast Auxiliary (STL and ICR) stations, and noting that these fixed services currently share use of the band with LPAS operations, what additional safeguards, if any, would be needed to insure that these fixed Aural Broadcast Auxiliary stations are protected if additional, non-broadcast classes of users are added to the band?

941–944 MHz Band and 952–960 MHz Band

111. *941–944 MHz band.* Most of this three megahertz—the two and a half megahertz between 941.5–944 MHz—is available for licensing for Private and Common Carrier Fixed Microwave Services. Broadcast auxiliary stations licensed prior to November 21, 1984 (including STL and ICR) may continue to operate in the 942–944 MHz band on a co-primary basis. After applicants were given the opportunity to file applications and to resolve disputes over frequency pairs internally and then by lottery, subsequent licenses were obtained on a first-come-first-served-basis, operating in different parts of this spectrum on channels that range from 25 kHz to 200 kHz in bandwidth. The Commission has issued approximately 820 licenses in this 941.5–944 MHz portion, where the vast majority are for Private Operational Fixed Point to Point Microwave Service, with some for Aural Broadcast Auxiliary Service (including STL and ICR), and a few for Common Carrier Fixed Point to Point Microwave Service. Fixed point-point links in these bands are typically used for long distance low data-rate links between locations that have line of sight capability. They employ directional antennas and operate with fairly high effective isotropic radiated power. Receive antennas are also directional, affording some rejection of unwanted signals off-axis from the main lobe of the antenna.

112. The other portion, the half megahertz between 941–941.5 MHz, is authorized for MAS operations. The MAS authorizations involve discrete portions of the 941–941.5 MHz band that is paired with spectrum in the 932–932.5 MHz band; more particularly, these paired blocks consist of thirty-six 12.5 kHz channel pairs (25 kHz total per pair) and one paired 50 kHz channel (100 kHz total per pair) in the 932.0–932.5 MHz and 941.0–941.5 MHz bands. The Commission designated twenty of the thirty-six 12.5 kHz channel pairs in these bands for public safety and/or private internal use. Five of these twenty are reserved for public safety services (as defined in Part 90), and the other fifteen are available for both private internal and traditional public safety services. With respect to the remaining channels consisting of sixteen 12.5 kHz paired channels and one 50 kHz paired channel (a total of 0.250 megahertz of spectrum in 941–941.5 MHz), the Commission has issued licenses on a geographic basis through a system of competitive bidding without any user restrictions, and these licensees are permitted to provide both fixed and mobile services on a co-primary basis. The 941.0 -941.5 MHz portion of the band is designated for communications from MAS master stations to remote stations; consequently, transmission from the master station is generally omni-directional, generally within a 25-mile radius, to many remote stations. The rules for MAS operations were adopted by the Commission in 1999. MAS historically has been used by the power, petroleum, and security industries for various alarm, control, interrogation and status reporting requirements as well as by the paging industry, and the licensing scheme adopted by the Commission attempted to accommodate these past and present uses. In the 941–941.5 MHz portion, there are 1,340 geographically-based MAS licenses and 1,175 site-based MAS licenses.

113. *952–960 MHz band.* Similarly, most of this eight megahertz of spectrum—6.8 megahertz of spectrum between 952.85–956.25 MHz and 956.45–959.85 MHz—is licensed for Private Operational Fixed Microwave Service (including business industrial and public safety) authorized under part

101. The Commission has issued approximately 2,850 Private Operational Fixed Point to Point Microwave Service licenses authorizing operations in the 952–960 MHz band.

114. The remaining portions of the band are authorized for MAS operations in three distinct portions, totaling 1.2 megahertz. Specifically, the MAS bands are divided into two groups with differing licensing and service characteristics. The first, commonly known as the 928/952/956 bands, include sixty-eight 12.5-kilohertz (kHz) channel pairs (25 kHz total per pair) in the 928–928.85 and 952–952.85 MHz bands (a total of 850 kilohertz in the 952–960 MHz band), and sixteen unpaired 12.5-kHz channels in the 956.25–956.45 MHz band (200 kHz total). These bands are reserved for ''private internal services,'' which are defined as those where licensees use their authorized frequencies purely for internal business purposes or public safety communications, and not for any for-hire (for-profit) or non-profit cost-shared application. The Commission awarded licenses to these bands on a first-come, first-served, site-by-site basis. The Commission has issued approximately 10,000 site-based MAS licenses in these bands.

115. The second MAS band, commonly known as the 928/959 MHz bands, consists of twelve 12.5 kHz channel pairs (25 kHz total per pair) in the 928.85–929 and 959.85–960 MHz bands (300 kHz total). The Commission licensed these bands on a geographic basis through a system of competitive bidding for use by for-profit CMRS and paging network incumbents. There are 484 geographically-based MAS licenses and approximately 120 site-based MAS licenses in this band. In addition, approximately 50 licenses permit part 22 paging operations in the 959.85–960 MHz band on a grandfathered basis.

116. In the *MAS Report and Order,* the Commission adopted flexible rules that permit licensees to conduct point-to-point and point-to-multipoint operations, and also to provide fixed or mobile services on a co-primary basis in the geographically licensed portions of the bands. The *MAS Report and Order* also grandfathered incumbent operations in the 928/952/956 MHz bands, and permitted those operations to expand services subject to the Commission's rules on interference protection and co-channel spacing. Although a system of geographic licenses using Economic Areas (EAs) awarded via auction now overlays the 928/959 bands and part of the 932/941 bands, we permitted incumbent licensees to remain in the in the 928/959 band indefinitely, but we did not permit any expansion of their services. The Commission expected that interference from these ''grandfathered'' operations would be minimal, given that they were subject to a co-channel mileage separation based on an assumed 25-mile service area.

117. The Commission proposes making unused portions of the 941–944 MHz and the 952–960 MHz bands available for licensed wireless microphone operations on a secondary basis, generally under the rules applicable for LPAS operations in the 944–952 MHz band. The Commission requests that commenters provide information about the potential availability of unused spectrum in these bands at locations where wireless microphones are used, and the extent to which it is suitable and could effectively be used for wireless microphone operations. The Commission seeks comment on the particular rules that it should adopt to facilitate wireless microphone operations in this spectrum that would also ensure that incumbent operations are not harmed. The Commission invites comment on the benefits of permitting such operations, as well as any specific concerns about how such operations might affect currently authorized users in these bands.

118. The Commission first seeks comment on whether there are potential benefits to making these bands available for wireless microphone operations to the same entities licensed for LPAS operations in the 944–952 MHz band. Considering the mix of services and licensees that currently operate in different segments in various portions of these bands, the Commission seeks comment on whether there nonetheless are many locations in these bands where spectrum is unused, potentially available, and in sufficient bandwidth (e.g., 200 kHz) suitable for wireless microphone uses similar to their uses in the TV bands and 944–952 MHz band. The Commission requests that commenters supporting wireless microphone operations in these bands explain fully how access to the available spectrum in these bands would be important for accommodating wireless microphone needs in the coming years, both in the near and longer term. Would the fact that this spectrum is adjacent to the 944–952 MHz band make this spectrum particularly suitable or involve valuable synergies (e.g., same spectrum propagation, more readily available equipment, more efficient management of wireless microphone operations, etc.)? And would the types of uses suitable for these bands be the same as for the 944–952 MHz band discussed?

119. Given that wireless microphones operate at low power over short distances, the Commission believes they are not likely to cause interference to the types of fixed or mobile operations that operate at higher power in these bands. Thus, it believes that wireless microphones should be able to co-exist and share access to the spectrum in these bands with incumbent services on a secondary basis without causing harmful interference. The Commission seeks comment. As this issue is considered, the Commission requests comment on how it can design rules for wireless microphone operations in these bands to enable effective sharing. Would users of wireless microphones often seek to operate in locations that overlap with existing services, or would they operate in other places not served by those operations?

120. Considering the different services and service rules that apply to portions of these bands, the Commission seeks comment on permitting wireless microphone operations on each of these portions. With the mix of point-to-point and point-to-multipoint services already operating in these bands, are there specific sub-bands that would be more suitable than others for sharing with wireless microphones?

121. With respect to those portions of the spectrum available for licensing for fixed microwave services other than MAS, which constitutes the majority of the spectrum in these bands, how much spectrum is unused by these fixed services at locations that could be effectively used for wireless microphone operations? To what extent can potential wireless microphone users determine the availability of suitable spectrum at particular locations? What issues and factors should we take into account to make spectrum available for wireless microphone operations while protecting the incumbent fixed services that operate in these bands?

122. The Commission similarly inquires about making the portions of the spectrum in these bands that are authorized for MAS operations also available for wireless microphone operations. For instance, considering that many MAS systems are used by utilities for Supervisory Control and Data Acquisition (SCADA) operations, we seek comment on whether these existing users operate in the same general geographic areas as wireless microphone users, or whether the wireless microphone operations would be separated geographically because these are different types of uses? Given the nature of MAS operations, how

much spectrum is unused and available for wireless microphone operations? Are there practical considerations, including the fact that there is only a relatively small amount of spectrum in discrete segments potentially unused and available, that would make authorizing wireless microphone operations more problematic or less practical in these bands? If so, are there ways in which the Commission could effectively address these concerns? Would the spectrum associated with the geographic area MAS licenses be suitable for wireless microphones, and if so could wireless microphone operations be accommodated on this spectrum through leasing arrangements with the existing market-based licensees? What other factors should we consider when determining whether and how to permit wireless microphone operations in these MAS portions?

123. The Commission also seeks specific comment on designing rules that would be necessary to address any interference concerns with incumbent operations that could arise. If it were to authorize wireless microphone operations in these bands, to what extent are protections necessary to prevent harmful interference to incumbent operations from the low power, short-range wireless microphone operations? Would certain types of services, such as fixed microwave services, generally not be prone to interference? Would other types of operations be more susceptible to interference, such as certain MAS operations involving SCADA operations, and would those operations benefit from rules that would provide protection (e.g., rules to specify minimum separation distances or creation of protection zones)? What specific technical requirements or limitations should we place on wireless microphone operations in the bands? On frequencies licensed for SCADA operations that involve transmissions between master stations and outdoor remotes, should we place limitations on power levels used by wireless microphones or limit wireless microphones to indoor uses? The Commission asks commenters to provide technical analyses to support their positions on these issues.

124. The Commission asks that commenters propose any specific technical rules that would apply to wireless microphone operations in these bands. As indicated, the Commission proposes permitting wireless microphones to operate under the technical rules for LPAS operations that apply to operations in the 944–952 MHz band (e.g., power limits, maximum bandwidth, Out of Band Emissions (OOBE)), which would include the ETSI standards that we propose to apply to such operations. The Commission seeks comment on this proposal, and whether these rules should apply in whole or in part with respect to these bands, or portions of these bands, and if not, why not? Commenters should explain and provide technical analyses on these issues. The Commission also seeks comment on the equipment issues that would pertain to wireless microphone operations in these bands, including the certification process. Commenters also should address any equipment issues pertaining to wireless microphone operations in these bands. What is the potential availability of equipment for operations in these bands? Realizing that it may depend on the particular rules, how long might it take for manufacturers to develop equipment that operates in these bands? Would the availability of devices operating in the adjacent 944–952 MHz band help speed development and distribution of these devices? To the extent that manufacturers may need to modify equipment designed for the 944–952 MHz band, or use equipment designed for use in other bands, what are the constraints on such modifications, and how long would it take to bring such modified equipment to market? As regards certification, should manufacturers be able to certificate equipment under the same rules and procedures for LPAS devices that operate in the 944–952 MHz band, or do they need to develop new equipment for these bands that would be certificated in a different manner?

Unlicensed Operations in the 902–928 MHz, the 2.4 GHz, and the 5 GHz Bands

125. The 902–928 MHz, 2.4 GHz (2400–2483.5 MHz), and 5 GHz (5725–5850 MHz) bands generally permit operations of unlicensed devices pursuant to two part 15 rules, §§ 15.247 and 15.249. Earlier this year, the Commission consolidated the rules for the digitally modulated devices that operate in the 5 GHz band under § 15.407. Wireless microphones are among the devices that operate on an unlicensed basis in these bands under these rules.

126. Wireless microphones operating in these bands pursuant to § 15.247, like other unlicensed devices operating under this rule, are required to operate as spread spectrum transmitters, and are limited to frequency hopping systems and systems using digital modulation. Digitally modulated systems must use a minimum bandwidth of 500 kHz but are not required to hop frequencies. Both frequency hopping and digitally modulated systems are permitted to use output powers of up to 1 watt, however, most devices use lower power for various design reasons, such as conserving battery life. Spread spectrum modulation reduces the power density of the transmitted signal at any frequency, thereby reducing the possibility of causing interference to other signals occupying the same spectrum. Similarly, at the receiver end, the power density of interfering signals is minimized, making spread spectrum systems relatively immune to interference from outside sources.

127. Wireless microphones operating in these bands pursuant to § 15.249, as with any other unlicensed device operation, is permitted subject to the field strength limits specified in this section. There are no requirements for devices operating under this provision to hop frequencies or use a minimum transmit bandwidth, and there are no maximum bandwidth or transmission duration limits. Devices operating under this rule could be either analog or digital devices. Many types of devices operate under this rule section including cordless telephones, video transmitters, wireless speaker and headphone systems, and automated utility meter reading equipment.

128. Section 15.407 provides general technical requirements for unlicensed national information infrastructure (U–NII) devices that operate in the 5 GHz band. The recently revised § 15.407 rules are intended to better ensure that unlicensed 5 GHz band devices do not cause harmful interference to authorized Federal and non-Federal users in these bands and to eliminate a loophole in the former rules that allowed devices to be certified under the § 15.247 rules and then modified to operate as U–NII devices without complying with all of the technical requirements of the U–NII rules.

902–928 MHz Band

129. The Commission seeks to develop a full record on the current and potential uses of the 902–928 MHz band for various wireless microphone uses. It ask that commenters provide information on devices currently in the marketplace that serve such needs. To what extent are these devices digital, operating as spread spectrum devices under the technical rules set forth in § 15.247, or analog or digital operating under § 15.249 requirements? What specific types of applications are these devices best suited, and what are the limitations on the types of applications for which they may be used? To what extent can devices operating in this

band address the needs, for instance, of non-professional users? The Commission asks that commenters provide relevant technical data regarding performance features (e.g., with respect to latency, voice fidelity, etc.) that inform and may affect the suitability of these devices for particular types of applications. To what extent is the effectiveness of the applications dependent on the operating environment (e.g., outdoor or indoor uses)? Are wireless microphone users whose needs can effectively be addressed through devices that operate in this band migrating their operations from other bands, such as the TV bands, to this band? What are manufacturers and those marketing wireless microphone devices promoting use of devices that use this band?

130. Have there been technological advances that have improved the ability of these devices to co-exist and share use of the band with the other users that also have access to the band? If so, what types? What kinds of advancements might be anticipated in the future that could increase the use of this band for wireless microphone applications?

131. To the extent devices operating in this band are effective in meeting wireless microphone applications, should manufacturers and those marketing wireless microphones do more to promote use of devices that operate in this band, or to indicate that devices operating in this band may be effective in addressing their needs that historically have operated in the TV bands? What steps, if any, should the Commission take to promote more use of this band for wireless microphone applications?

2.4 GHz Band

132. As with our discussion on the 902–928 MHz band, the Commission also seeks to develop a full record on the current and potential uses of the 2.4 GHz band for various wireless microphone uses. It asks that commenters provide information on devices currently in the marketplace, and the extent are these devices digital, operating as spread spectrum devices under the technical rules set forth in § 15.247, or analog or digital operating under § 15.249 requirements. For what types of specific applications are 2.4 GHz wireless microphones best suited, and what limitations are associated with their use, including any that may result from the nature of signal propagation in the band. To what extent can devices operating in this band address the needs of non-professional users? As above, we ask that commenters provide relevant technical data regarding performance features (e.g., with respect to latency, voice fidelity, etc.) that inform and may affect the suitability of these devices for particular types of applications. What types of operating environment (e.g., outdoor or indoor uses) affect their effectiveness for specific applications? How are manufacturers and those marketing wireless microphone devices promoting use of devices that use this band?

133. The Commission also asks that commenters discuss technological advances that have improved the ability of these devices to co-exist and share use of the band with the other users that operate in the band. Are advancements anticipated that could increase the use of this band for wireless microphone applications? Finally, to the extent devices operating in this band are effective in meeting wireless microphone applications, should more be done to promote use of devices that operate in this band?

5 GHz Band

134. The Commission also asks that commenters provide information on the current and potential uses of this band for different types of wireless microphone operations. To what extent are devices that function as wireless microphones operating in this band today, and for what kinds of applications? Considering the available bandwidth, the propagation features associated with this spectrum, and other relevant factors, for what types of applications is this band well-suited? What types of users are most likely to make use of wireless microphones in this band? In what types of operational environments do these devices work best? Are there technological advances forthcoming that could create more opportunities for using this spectrum for wireless microphone applications? Should more be done to promote use of this band for wireless microphone applications?

1920–1930 MHz Unlicensed PCS Band

135. Currently the major use of the 1920–1930 MHz band is for unlicensed cordless telephones that operate under part 15 of the Commission's rules many manufacturers make wireless microphones using this spectrum.

136. The Commission invites comment on the current and potential uses of the 1920–1930 MHz UPSC band for wireless microphone applications. The Commission seeks comment on current uses of the band for wireless microphones, including the types of purposes for which they are used as well as the types of venues in which they are used. How many microphones generally can be deployed at the same time in a particular area? To the extent that wireless microphones operating in this band may not be sufficient for high-end, professional broadcast, music, or theater uses, are there other types of uses for which they provide effective wireless microphone communications capabilities? What is the range of audio capabilities for wireless microphone devices that operate in this band under our rules? For instance, are there potential advances in technology, such as improvements in the digital protocol to better enable high quality audio? In sum, the Commission invites comments generally on the types of applications for which wireless microphones using this band may be best suited. Should the Commission consider any technical revisions that could make this band more useful for wireless microphone applications without adversely affecting operations of other users in the band?

1435–1525 MHz Band

137. The Commission proposes, as one option, making the 1.4 GHz band spectrum available for use by wireless microphones on a secondary licensed basis, and seek comment. Because of the importance of ensuring that the AMT systems are protected against harmful interference, and given that most wireless microphone operations can be accommodated within other spectrum, the Commission proposes that use of this band be limited to licensed professional users at specified locations and times, and include specified safeguards designed to protect AMT use of the band. The Commission seeks comment on how and under what conditions this band can be shared, and on the types of applications best suited for this band.

138. Our proposal to allow wireless microphones to operate in this spectrum is based on several critical factors. We recognize that professional use for certain large events (e.g., major sports or theater productions) often involve use of more than 100 wireless microphones. Where these have previously operated in the TV bands, there is no assurance that sufficient spectrum will remain to accommodate this extent of use, nor is it certain that the other provisions for wireless microphones could accommodate such use. Limiting the licensing for these types of applications, which are typically associated with specific locations, should make sharing of the spectrum manageable. Although we would authorize such use on a secondary basis, in this instance we believe that frequency coordination with federal and non-federal users is critical and is consistent with the

practice that already has been used for special temporary authority in this band, although on a more limited basis. In addition, the Commission believes it is necessary to ensure that a mechanism must be established to ensure that wireless microphone systems marketed for use in this spectrum can only be operated after successful coordination, such as through an electronic key or other means. The Commission also seeks to ensure that any wireless microphones operating in this spectrum are spectrally efficient and frequency agile when sharing the spectrum. The Commission discusses these topics in detail below. Where it asks general questions they should be viewed through the prism of these principles.

139. Generally, as the Commission considers authorizing wireless microphone operations in the 1.4 GHz band on a secondary use basis, what issues should it consider when evaluating the compatibility of wireless microphone operations in the same band as AMT? What limitations might the Commission consider imposing to ensure that wireless microphone operations would not cause harmful interference to AMT?

140. To what extent is the 1.4 GHz spectrum suited for wireless microphone operations? What type of wireless microphone uses might be best suited to operate in this band, and what types of uses would be less well-suited or unsuitable? How would proponents of access to this spectrum plan to make use of the band for wireless microphone operations? What are the technical advantages and disadvantages of using 1.4 GHz band spectrum for wireless microphone operations, in terms of signal propagation, types of operations that could be deployed, battery power, form factors, body absorption, or other aspects that would inform the types of wireless microphone uses to which the spectrum might be put?

141. The Commission proposes that wireless microphone operations be secondary, and thus must protect the primary AMT services that operate in the band. As it considers the appropriate framework for wireless microphone operations in the band, we note that the Commission already has permitted secondary, low power short-range devices to share use of another band where AMT operations were primary when in 2012 it authorized Medical Body Area Network (MBAN) devices to operate in the 2360–2390 MHz portions of the 2360–2400 MHz band. In permitting MBAN devices to share access to that spectrum, the Commission was careful in developing rules that limited the locations where MBAN systems could operate and in designing a coordination process that would ensure that primary AMT operations would be protected from interference.

142. As a general matter, the Commission proposes only limited use of the 1.4 GHz band for wireless microphone applications. While it seeks to provide wireless microphone users in need of additional spectrum resources with access to the 1.4 GHz band spectrum to help accommodate those needs, at the same time the Commission is not proposing to open this particular band either for widespread or for itinerant uses throughout the nation. Given the paramount need to protect AMT operations, the Commission is proposing only limited access for wireless microphone operations. In particular, it proposes that wireless microphone uses be restricted to specific fixed locations, such as large venues (whether outdoor or indoor), where there may a need to deploy large numbers of microphones, e.g., 100 or more. In addition, the Commission proposes allowing operations at those locations only at specified times. The Commission seeks comment on these proposals.

143. Prior coordination with AFTRCC will be required. The Commission seeks to develop appropriate rules that will ensure through this process that wireless microphone operations will not cause interference to the primary AMT operations in the band. In particular, it seeks comment on coordination mechanisms that can ensure that wireless microphone operations only occur at the locations and times where authorized through the coordination process, and would be effective in preventing the use of these devices at any other location or time without authorization.

144. As noted, the Commission authorized MBAN devices to operate on a secondary basis in the 2360–2390 MHz band provided that they register the devices and follow a coordination framework. With regard to registration, MBAN device operators are required to register each device with the frequency coordinator and provide specified information—including the specific frequencies to be used, the location of the devices, the power levels used, and point of contact information regarding the entity responsible for the MBAN device operations. The Commission codified certain coordination procedures as well. These begin with the initial determination of whether the MBAN location is within line-of-site of AMT operations, and the potential interference risks that would be associated with MBAN operations at that location. The Commission also provided the frequency coordinators with significant flexibility to work out mutually agreeable coordination agreements and MBAN devices' operating parameters at particular locations. The Commission recognized that specific tools, such as electronic keys, could be useful to coordinators as they sought to achieve mutually agreeable coordination agreements, and required that MBAN devices cease transmission in the absence of a control message. At the same time, the Commission did not codify requirements for an electronic key and relied on frequency coordinators to work out the MBAN operating parameters through their agreements as needed. To what extent are the rules for MBAN operations appropriate with regard to permitting wireless microphone use in the 1.4 GHz band at specified locations, frequencies, and times, pursuant to specified operational parameters? The Commission asks that commenters explain in detail the coordination procedures that they assert should apply with regard to operations in the 1.4 GHz band.

145. The Commission also seeks comment on the extent to which the Commission might prescribe particular tools to ensure that wireless microphones operate only at the locations and times authorized, and not anywhere else. For instance, the Commission seeks comment on requiring that the wireless microphone systems, which often are moved from one location to another (e.g., when used to cover different events), could only operate through use of an automatic mechanism (such as an electronic key, and location-awareness capability, or similar mechanisms) that would serve to prevent wireless microphones from operating unless on approved frequencies in the 1.4 GHz band at the approved location/venue(s) during approved time(s). What kind of technologies can achieve this purpose in an effective manner? If we were to adopt such a requirement, should the authorized operations be enabled only through permission granted by the FCC or an FCC-certified entity once AFTRCC has concurred with the particular wireless microphone operations? Are there other means of coordinating operations that would ensure that the microphones only operate where and when authorized? The Commission seeks comment on these proposals, including how an automatic mechanism might be included within design of a wireless microphone system. In

addition, the Commission invites comment on whether it should adopt point-of-sale restrictions that would enable only entities licensed to operate in this band to obtain the devices.

146. In keeping with the types of wireless microphone operations that the Commission envisions for this band, it proposes limiting eligibility to professional users, including broadcasters, professional television and cable programmers, and professional sound engineering companies, and operators at major venues that manage and coordinate wireless microphone operations, i.e., the entities eligible for licensed LPAS operations in the TV bands. The Commission invites comment on this proposal.

147. To the extent the Commission decides to authorize wireless microphone operations in this band, it seeks comment on the technical rules that would apply to devices that would use the band. Commenters should submit detailed discussions of recommendations for the applicable technical rules. In designing technical rules, what types of technical concerns should we consider and address to ensure that the primary AMT operations protected? The Commission requests detailed information about the type(s) of wireless microphone equipment that could use the band. What power levels and bandwidths should we permit for wireless microphones? To what extent should we permit certain devices already on the market today to access the band? Should the technical rules be the similar to wireless microphones that operate in other bands?

148. In particular, the Commission seeks comment on adopting the technical rules for LPAS device operations in the TV bands, as well as the ETSI standards that it is proposing to adopt for those devices. To what extent are some or all of these technical standards appropriate for wireless microphones operating in the 1.4 GHz band? The Commission asks that commenters provide any relevant technical information supporting their positions.

149. To preserve maximum flexibility for wireless microphone operations in the band, should the Commission consider requiring wireless microphones to have the capability of tuning across the band? The Commission also seeks comment on requiring wireless microphones that are designed to operate in the 1.4 GHz band to have modular transmitting components that, if necessary, could be replaced to enhance frequency agility. How long would it take to develop devices that would operate consistent with the proposals we discussed above? Should there be an interim process for permitting wireless microphone operations in the band as any necessary new devices are being made? In addition, the Commission invites comment on the certification process that should be employed.

150. Consistent with its proposal, the Commission envisions adding a secondary mobile except aeronautical mobile service allocation to the 1435–1525 MHz band for limited use under the service rules it adopts for the band. The Commission also request comment on any other regulatory or technical issues that would be relevant to our consideration of whether to authorize wireless microphone operations in the 1.4 GHz band. Commenters should provide detailed bases and explanations for their proposals and views.

3.5 GHz Band

151. In the *3.5 GHz Band FNPRM* adopted in April 2014, the Commission sought comment on a three-tiered authorization framework that would allow different types of users to access portions of the 3550–3650 MHz Band. To the extent that the band was not being used by incumbent users (primary operations, including incumbent federal users and grandfathered Fixed Satellite Service earth stations) under the Incumbent Access tier, the Commission proposed making spectrum available through the Priority Access and General Authorized Access (GAA) tiers outside of the specified geographic exclusion zones. The Commission also invited comment on whether to allow certain users (''Contained Access Users'') to receive interference protection for their device operations within the confines of their facilities on a portion (up to 20 megahertz) of the frequencies included in the GAA tier.

152. The Commission notes the comments have been filed in the 3.5 GHz band proceeding (GN Docket No. 12–354) on potential uses of this band by wireless microphone users. Shure indicated that the GAA tier, for instance, could potentially support certain wireless applications, and asserted that were the Commission to establish a class of ''Contained Access Users'' then indoor wireless microphone use should qualify for such access.

153. All of the issues regarding the policies and rules for operations in the 3.5 GHz proceeding will be decided in that proceeding, based on the record in that proceeding, and the Commission is not seeking comment in this instant proceeding on those issues. Nonetheless, considering that the Commission is seeking to develop a comprehensive understanding of the potential landscape for different types of wireless microphone operations in different bands, it seeks general comment on whether and how wireless microphone operations potentially could be employed in the 3.5 GHz band to help accommodate particular needs of users. Without prejudging the specific rules that the Commission may adopt in the 3.5 GHz proceeding, the Commission invites comment on any impact the proposed rules for the 3.5 GHz band would have on the broader aims of this proceeding. If 3.5 GHz spectrum were made available, how much of a wireless microphone operator's needs could potentially be accommodated in this band, for instance, given the propagation characteristics of the band? If operations were permitted in this band, to what extent might this band potentially serve as a supplement spectrum resource for certain types of uses? To the extent that rules for the 3.5 GHz band are adopted that can help meet wireless microphone users' needs, how long might it take for user equipment to be developed and available for use? To avoid a bifurcated record on issues related to the 3.5 GHz band, the Commission asks that commenters submit any comments on these issues in this docket as well as in the 3.5 GHz band proceeding.

6875–7125 MHz Band

154. The Commission proposes to permit licensed wireless microphone operations on available channels in this band, on a secondary basis, for entities that are eligible to hold BAS or CARS licenses, and seek comment. Considering the existing fixed and mobile services in the band that currently operate in different portions of this band, and the likelihood of significant areas of unused spectrum throughout this band that potentially could be made available for relatively low power, short-range wireless microphone operations, the Commission request comment on whether access to this spectrum could help accommodate certain types of wireless microphone applications without interfering with existing services. The Commission also seeks comment on the applicable rules that should apply, were we to decide to grant such authorization.

155. To what extent would access to the 7 GHz band help address needs of wireless microphone operators? Considering the propagation features or other factors associated with this spectrum, what types of wireless microphone applications may be well-suited for operations in this band? Given that BAS and CARS licensees

already use the 7 GHz spectrum for certain types of video applications and programming production, would there be synergies in permitting wireless microphone operations that could supplement those existing applications? How much spectrum in the 7 GHz band may be potentially available at those kinds of locations, whether indoors or outdoors, where users may have need for wireless microphones?

156. What particular rules would facilitate wireless microphone operations in the band while also protecting existing services? Could we make spectrum in any part of the 7 GHz band available for wireless microphone operations on a secondary, non-interfering basis, under rules drawn from the LPAS technical rules for operations in the TV bands or on the 944–952 MHz band? To what extent would low power wireless microphone operations pose the potential of interfering with any of the current mix of fixed and mobile BAS services and private and commercial fixed microwave that operate in the band?

157. Alternatively, should the Commission consider making certain portions of the 7 GHz band available for wireless microphone operations, both as a means to facilitate wireless microphone operations as well as to preclude any possibility of harmful interference to existing operations? For instance, are there certain 25-megahertz channels, or smaller-sized portions of such channels, that we should make available for wireless microphone operations, and if so, how much and where? Would some channels or portions of channels be preferable for wireless microphone operations? As noted, while BAS and CARS are authorized to operate on the entire 25 megahertz in a channel, FS services may operate on 5, 8.33, and 25 megahertz channels. Are there opportunities for wireless microphone operations on portions of particular channels to the extent not being used by incumbent licensees at a given location? For instance, if an incumbent licensee were using only 5 or 8.33 megahertz channels, could wireless microphones operate on some balance of that 25-megahertz channel without interfering with existing services? Are there particular segments in the 7 GHz band that would be more suitable, such as the 25 megahertz segments that are currently reserved for BAS use nationwide? Are other channels or portions of channels more suitable, and if so should we take steps to restrict additional authorizations in that spectrum or otherwise open that spectrum for wireless microphone uses? If commenters have specific ideas about whether certain portions of the 7 GHz band should be made available, the Commission asks that they submit a full discussion of which portions, and how that might affect any existing BAS, CARS, or FS authorized in those portions of the band.

158. To what extent should coordination of wireless microphone operations be required? Should we require formal or informal coordination of operations? We also seek comment on whether wireless microphone users could share operations among themselves on the same private-sector, frequency-coordinated basis that exists for the use of BAS mobile shared spectrum.

159. The Commission is proposing that any wireless microphone operations in these bands be licensed to entities eligible for BAS or CARS licensees. It generally would expect that these are the entities that may wish to operate wireless microphones in the band for some of their production-related services. The Commission also believes that licensing wireless microphone operations to these entities would help address interference or coordination concerns that may arise when making use of the 7 GHz band spectrum. The Commission seeks comment on this proposal. The Commission also invites comment on alternative proposals.

160. The Commission also invites comment on the technical rules that would apply to wireless microphone operations in the band. In particular, it seeks comment on whether the technical rules should be modeled on those that apply to LPAS operations, including the ETSI standards that we are proposing. The Commission asks that commenters provide information on any proposed rules and the rationale for adopting such rules. Commenters should also address any potential interference concerns that could arise. If we were to allow wireless microphone operations in the band, would any incumbent operations need geographic exclusion zones? Apart from exclusion zones, is there interference criteria that could facilitate sharing? What OOBE limits would be appropriate to protect incumbent services in the bands directly adjacent to wireless microphone operations? Considering the propagation characteristics in the 7 GHz band and recognizing that operation in this band typically requires line of sight between the transmitter and receiver, would limiting wireless microphones to indoor use create greater sharing possibilities? The Commission asks commenters to provide technical analyses to support their position on these issues.

161. In addition, the Commission seeks comment on equipment availability for wireless microphones in these bands. Does wireless microphone equipment already exist for these bands? How much time would manufacturers need to develop new equipment for these bands?

Ultra-Wideband

162. *Background.* The Commission's rules for ultra-wideband (UWB) unlicensed devices are set forth in part 15, subpart F. UWB devices operate by employing very narrow or short duration pulses that result in very large or wideband transmission bandwidths. UWB technology enables development of an array of applications, including imaging systems, vehicular radar systems, and communications and measurement systems. Operating pursuant to the technical rules set forth in part 15, UWB devices can use spectrum occupied by existing radio services without causing harmful interference, thereby permitting scarce spectrum resources to be used more efficiently.

163. Wireless microphones operating under these rules would be required to operate pursuant to the UWB rules for communications systems, which permit operations in the 3.1–10.6 GHz band. Under the UWB rules, these devices must be designed to ensure that operation can occur indoors only, or must consist of hand-held devices that may be employed for such activities as peer-to-peer operation. The Commission notes that at least one wireless microphone manufacturer has developed and markets wireless microphones that operate under these rules.

164. The Commission seeks comment on the current and potential uses of UWB devices for wireless microphone applications. Recognizing that UWB operates across a number of frequencies, the Commission asks commenters to discuss the ways in which UWB devices could be used effectively for wireless microphone uses. Are there particular uses for which wireless microphones operating under UWB rules are well suited, such as indoor and/or short-range operations? What are the benefits and constraints associated with the UWB rules, including the wide bandwidths associated with operations and the propagation aspects related to operating in these high frequency bands? Are manufacturers promoting the use of UWB wireless microphones for particular applications? Finally, we invite comment regarding steps that the

Commission should take to facilitate use of UWB devices for wireless microphone uses.

Other Potential Bands

165. In this section, the Commission invites comment on whether there are other bands not currently available for wireless microphone operations that may be useful in helping their use. The Commission seeks comment on bands that might offer opportunities both in the nearer term and over the longer term.

166. For instance, in 2008 the Public Interest Spectrum Coalition (PISC) filed a petition for rulemaking to create a general wireless microphone service in the 2020–2025 MHz band. PISC argued that, as a result of the Commission's proposal to license the 2175–2180 MHz band on an unpaired basis, the 2020–2025 MHz band could be allocated for wireless microphones on a primary basis and free of white space devices and interference. Would this band be suitable for wireless microphone use? If so, the Commission asks that commenters address the technical suitability of this five megahertz band, the potential equipment availability, and other issues that would have to be addressed. The Commission also asks commenters to address how a decision to permit wireless microphones to operate in the 2020–2025 MHz band would impact or be affected by the Commission's earlier decision to allocate those five megahertz for non-federal fixed and mobile service.

167. To the extent that commenters propose additional bands for consideration, we ask that they provide a full explanation for the proposal. In particular, the Commission seeks comment on the ways in which the band or bands could be helpful in accommodating wireless microphone operations while advancing the Commission's spectrum management goals, including promoting efficient use of spectrum.

Procedural Matters

Paperwork Reduction Analysis

168. The *NPRM* contains proposed new information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and OMB to comment on the proposed information collection requirements contained in this document, as required by the PRA. In addition, pursuant to the Small Business Paperwork Relief Act, the Commission seeks specific comment on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees.

Initial Regulatory Flexibility Analysis

169. As required by the Regulatory Flexibility Act (RFA), the Commission has prepared this present Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on small entities by the policies and rules proposed in the *NPRM*.[1] Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments provided on the first page of this NPRM. The Commission will send a copy of the *NPRM,* including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).[2] In addition, the *NPRM* and IRFA (or summaries thereof) will be published in the **Federal Register.**[3]

Need for, and Objectives of, the Proposed Rules

170. This proceeding is initiated to explore additional steps we can take to accommodate the needs of wireless microphone users over the coming years by ensuring that they have access to available spectrum resources that they need.[4] Wireless microphones play an essential role in enabling broadcasters and other video programming networks to serve consumers, including helping to cover breaking news and broadcasting live sports events. They are used to significantly enhance event productions in a variety of settings—including theaters and music venues, film studios, conventions, corporate events, houses of worship, and internet webcasts. They also have become integral to creating high quality content that consumers demand and value, and as part of that content production process contribute substantially to our economy.[5] Recent actions by the Commission, and in particular the repurposing of broadcast television band spectrum for wireless services set forth in the *Incentive Auction R&O,* will significantly alter the regulatory environment in which wireless microphones operate[6] and we see an urgent need to assess new options for wireless microphone users going forward.

171. Wireless microphone users rely heavily on access to unused channels in the television band to provide their important services. Following the incentive auction, with the repacking of the television band and the repurposing of current television spectrum for wireless services, there will be fewer frequencies in the UHF band available for use for wireless microphone operations. In taking several steps in the *Incentive Auction R&O* to accommodate wireless microphone operations—including providing more opportunities to access spectrum on the channels that will remain allocated for television post-auction and making the 600 MHz Band guard bands available for wireless microphone operations—the Commission also recognized that the reduction of total available UHF band spectrum will require many wireless microphone users to make adjustments over the next few years regarding the spectrum that they access and the equipment they use.[7] To help ensure that wireless microphone users could make these adjustments, the Commission provided that users could continue to access spectrum repurposed for wireless services for a substantial period of time as they transition affected services to alternative spectrum.[8] The Commission promised to initiate this proceeding to explore steps that it can take to address wireless microphone users' longer term needs, including accessing spectrum resources in additional frequency bands.[9]

Legal Basis

172. The proposed action is authorized under sections 4(i), 7(a) 301, 303(f), 303(g), 303(r), 307(e) and 332 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 157(a),

[1] *See* 5 U.S.C. 603. The RFA, *see* 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. 857 (1996).

[2] *See* 5 U.S.C. 603(a).

[3] *See id.*

[4] *See* Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions, GN Docket No. 12–268, *Report and Order* (FCC 14–50), 29 FCC Rcd 6567, 6704 para. 316 (adopted May 15, 2014) (*Incentive Auction R&O*) (stating the Commission's intent to initiate a proceeding to explore steps to accommodate the long-term needs of wireless microphone users). When we use the term ''wireless microphones'' in this proceeding, we collectively refer to wireless microphones and related audio devices.

[5] *See, e.g.,* Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions, GN Docket No. 12–268, *Report and Order* (FCC 14–50), 29 FCC Rcd 6567, 6696 para. 300 (adopted May 15, 2014) (*Incentive Auction R&O*).

[6] *See generally* Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions, GN Docket No. 12–268, *Report and Order* (FCC 14–50), 29 FCC Rcd 6696–6704 paras. 299–316; 6844–6847 para. 682–688, (adopted May 15, 2014) (*Incentive Auction R&O*).

[7] *See Incentive Auction R&O,* 29 FCC Rcd at 6567 paras. 299–315.

[8] *See Incentive Auction R&O,* 29 FCC Rcd at 6567 paras. 682–688.

[9] *Incentive Auction R&O,* 29 FCC Rcd at 6567 para. 316.

301, 303(f), 303(g), 303(r), 307(e), and 332.

Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

173. 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, if adopted.[10] The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' [11] In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.[12] 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.[13]

174. Small Businesses, Small Organizations, and Small Governmental Jurisdictions. Our action may, over time, affect small entities that are not easily categorized at present. We therefore describe here, at the outset, three comprehensive, statutory small entity size standards.[14] First, nationwide, there are a total of 28.2 million small businesses, according to the SBA.[15] In addition, a ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.''[16] Nationwide, as of 2012, there were approximately 2,300,000 small organizations.[17] Finally, the term ''small governmental jurisdiction'' is defined generally as ''governments of cities, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.''[18] Census Bureau data for 2012 indicate that there were 90,056 local governments in the United States.[19] Thus, we estimate that most governmental jurisdictions are small.

175. LPAS Licensees. There are a total of more than 1,200 Low Power Auxiliary Station (LPAS) licenses in all bands and a total of over 600 LPAS licenses in the UHF spectrum.[20] Existing LPAS operations are intended for uses such as wireless microphones, cue and control communications, and synchronization of TV camera signals. These low power auxiliary stations transmit over distances of approximately 100 meters.[21]

176. Low Power Auxiliary Device Manufacturers: Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing. The Census Bureau defines this category as follows: ''This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment.''[22] The SBA has developed a small business size standard for Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, which is: all such firms having 750 or fewer employees.[23] According to Census Bureau data for 2007, there were a total of 939 establishments in this category that operated for the entire year.[24] Of this total, 912 establishments had employment of less than 500, and an additional 10 establishments had employment of 500 to 999.[25] Thus, under this size standard, the majority of firms can be considered small.

177. Low Power Auxiliary Device Manufacturers: Other Communications Equipment Manufacturing. The Census Bureau defines this category as follows: ''This industry comprises establishments primarily engaged in manufacturing communications equipment (except telephone apparatus, and radio and television broadcast, and wireless communications equipment).'' [26] The SBA has developed a small business size standard for Other Communications Equipment Manufacturing, which is: all such firms having 750 or fewer employees.[27] According to Census Bureau data for 2007, there were a total of 452 establishments in this category that operated for the entire year.[28] Of this total, 448 establishments had employment below 500, and an additional 4 establishments had employment of 500 to 999.[29] Thus, under this size standard, the majority of firms can be considered small.

178. Television Broadcasting. This Economic Census category ''comprises establishments primarily engaged in broadcasting images together with sound. These establishments operate television broadcasting studios and facilities for the programming and transmission of programs to the public.'' [30] The SBA has created the

[10] 5 U.S.C. 603(b)(3).

[11] 5 U.S.C. 601(6).

[12] 5 U.S.C. 601(3) (incorporating by reference the definition of ''small business concern'' in 15 U.S.C. 632). Pursuant to the RFA, 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**.'' 5 U.S.C. 601(3).

[13] Small Business Act, 15 U.S.C. 632 (1996).

[14] *See* 5 U.S.C. 601(3)–(6).

[15] *See* SBA, Office of Advocacy, ''Frequently Asked Questions,'' *http://www.sba.gov/sites/default/files/FAQ_March_2014_0.pdf* (last visited May 2, 2014; figures are from 2011).

[16] 5 U.S.C. 601(4).

[17] National Center for Charitable Statistics, The Nonprofit Almanac (2012).

[18] 5 U.S.C. 601(5).

[19] U.S. Census Bureau, Government Organization Summary Report: 2012 (rel. Sep. 26, 2013), *http://www2.census.gov/govs/cog/g12_org.pdf* (last visited May 2, 2014).

[20] FCC, Universal Licensing System (ULS), *available at http://wireless.fcc.gov/uls/index.htm?job=home* (last visited May 13, 2014).

[21] 47 CFR 74.801.

[22] U.S. Census Bureau, 2012 NAICS Definitions: 334220 Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, *http://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=334220* &search=2012 (last visited May 6, 2014).

[23] 13 CFR 121.201, NAICS code 334220.

[24] U.S. Census Bureau, Table No. EC0731SG3, Manufacturing: Summary Series: General Summary: Industry Statistics for Subsectors and Industries by Employment Size: 2007 (NAICS code 334220), *http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2007_US_31SG3*. The number of ''establishments'' is a less helpful indicator of small business prevalence in this context than would be the number of ''firms'' or ''companies,'' because the latter take into account the concept of common ownership or control. Any single physical location for an entity is an establishment, even though that location may be owned by a different establishment. Thus, the numbers given may reflect inflated numbers of businesses in this category, including the numbers of small businesses.

[25] *Id.* An additional 17 establishments had employment of 1,000 or more.

[26] U.S. Census Bureau, *2012 NAICS Definitions: 334290 Other Communications Equipment Manufacturing, http://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=334290&search=2012* (last visited May 6, 2014).

[27] 13 CFR 121.201, NAICS code 334290.

[28] U.S. Census Bureau, Table No. EC0731SG3, Manufacturing: Summary Series: General Summary: Industry Statistics for Subsectors and Industries by Employment Size: 2007 (NAICS code 334290), *http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2007_US_31SG3&prodType=table* (last visited May 6, 2014). The number of ''establishments'' is a less helpful indicator of small business prevalence in this context than would be the number of ''firms'' or ''companies,'' because the latter take into account the concept of common ownership or control. Any single physical location for an entity is an establishment, even though that location may be owned by a different establishment. Thus, the numbers given may reflect inflated numbers of businesses in this category, including the numbers of small businesses.

[29] *Id.* There were no establishments that had employment of 1,000 or more.

[30] U.S. Census Bureau, *2012 NAICS Definitions: 515120 Television Broadcasting,* (partial definition), *http://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=515120&search=2012* (last visited May 6, 2014).

following small business size standard for Television Broadcasting firms: those having $38.5 million or less in annual receipts.[31] The Commission has estimated the number of licensed commercial television stations to be 1,388.[32] In addition, according to Commission staff review of the BIA Advisory Services, LLC's *Media Access Pro Television Database* on March 28, 2012, about 950 of an estimated 1,300 commercial television stations (or approximately 73 percent) had revenues of $14 million or less.[33] We therefore estimate that the majority of commercial television broadcasters are small entities.

179. We note, however, that in assessing whether a business concern qualifies as small under the above definition, business (control) affiliations must be included.[34] Our estimate, therefore, likely overstates the number of small entities that might be affected by our action because the revenue figure on which it is based does not include or aggregate revenues from affiliated companies. In addition, an element of the definition of ''small business'' is that the entity not be dominant in its field of operation. We are unable at this time to define or quantify the criteria that would establish whether a specific television station is dominant in its field of operation. Accordingly, the estimate of small businesses to which rules may apply does not exclude any television station from the definition of a small business on this basis and is therefore possibly over-inclusive to that extent.

180. In addition, the Commission has estimated the number of licensed noncommercial educational (NCE) television stations to be 396.[35] These stations are non-profit, and therefore considered to be small entities.[36]

181. There are also 2,414 low power television stations, including Class A stations and 4,046 television translator stations.[37] Given the nature of these services, we will presume that all of these entities qualify as small entities under the above SBA small business size standard.

182. Cable Television Distribution Services. Since 2007, these services have been defined within the broad economic census category of Wired Telecommunications Carriers; that category is defined as follows: ''This industry comprises establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired telecommunications networks. Transmission facilities may be based on a single technology or a combination of technologies.'' [38] The SBA has developed a small business size standard for this category, which is: All such firms having 1,500 or fewer employees.[39] Census data for 2007 shows that there were 3,188 firms that operated for the duration of that year.[40] Of those, 3,144 had fewer than 1,000 employees, and 44 firms had more than 1,000 employees. Thus under this category and the associated small business size standard, the majority of such firms can be considered small.

183. Cable Companies and Systems. The Commission has also developed its own small business size standards, for the purpose of cable rate regulation. Under the Commission's rules, a ''small cable company'' is one serving 400,000 or fewer subscribers, nationwide.[41] Industry data indicate that of approximately 1,100 cable operators nationwide, all but ten are small under this size standard.[42] In addition, under the Commission's rules, a ''small system'' is a cable system serving 15,000 or fewer subscribers.[43] Current Commission records show 4,945 cable systems nationwide.[44] Of this total, 4,380 cable systems have fewer than 20,000 subscribers, and 565 systems have 20,000 or more subscribers, based on the same records. Thus, under this standard, we estimate that most cable systems are small entities.

184. Cable System Operators. The Communications Act of 1934, as amended, also contains a size standard for small cable system operators, which is ''a cable operator that, directly or through an affiliate, serves in the aggregate fewer than 1 percent of all subscribers in the United States and is not affiliated with any entity or entities whose gross annual revenues in the aggregate exceed $250,000,000.'' [45] The Commission has determined that an operator serving fewer than 677,000 subscribers shall be deemed a small operator, if its annual revenues, when combined with the total annual revenues of all its affiliates, do not exceed $250 million in the aggregate.[46] Industry data indicate that of approximately 1,100 cable operators nationwide, all but ten are small under this size standard.[47] We note that the Commission neither requests nor collects information on whether cable system operators are affiliated with entities whose gross annual revenues exceed $250 million,[48] and therefore we are unable to estimate more accurately the number of cable system operators that would qualify as small under this size standard.

185. Direct Broadcast Satellite (''DBS'') Service. DBS service is a nationally distributed subscription service that delivers video and audio programming via satellite to a small parabolic ''dish'' antenna at the

[31] 13 CFR 121.201 (NAICS code 515120) (updated for inflation in 2010).

[32] *See FCC News Release,* Broadcast Station Totals as of December 31, 2013 (rel. January 8, 2014), *http://transition.fcc.gov/Daily_Releases/Daily_Business/2014/db0108/DOC-325039A1.pdf.*

[33] We recognize that BIA's estimate differs slightly from the FCC total given.

[34] ''[Business concerns] are affiliates of each other when one concern controls or has the power to control the other or a third party or parties controls or has to power to control both.'' 13 CFR 21.103(a)(1).

[35] *See FCC News Release,* Broadcast Station Totals as of December 31, 2013 (rel. January 8, 2014), *http://transition.fcc.gov/Daily_Releases/Daily_Business/2014/db0108/DOC-325039A1.pdf.*

[36] *See generally* 5 U.S.C. 601(4), (6).

[37] *See FCC News Release,* Broadcast Station Totals as of December 31, 2013 (rel. January 8, 2014), *http://transition.fcc.gov/Daily_Releases/Daily_Business/2014/db0108/DOC-325039A1.pdf.*

[38] U.S. Census Bureau, *2012 NAICS Definitions: 517110 Wired Telecommunications Carriers, http://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=517110&search=2012* (last visited May 5, 2014).

[39] U.S. Small Business Administration, Table of Small Business Size Standards Matched to North American Industry Classification System Codes, at 28 (2014), *http://www.sba.gov/sites/default/files/files/size_table_01222014.pdf.*

[40] *See* U.S. Census Bureau, American FactFinder, 2007 Economic Census of the United States, Table No. EC0751SSSZ5, Establishment and Firm Size: Employment Size of Firms for the United States: 2007, NAICS code 517110, *http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2007_US_51SSSZ5* (last visited May 7, 2014).

[41] 47 CFR 76.901(e). The Commission determined that this size standard equates approximately to a size standard of $100 million or less in annual revenues. Implementation of Sections of the 1992 Cable Act: Rate Regulation, *Sixth Report and Order and Eleventh Order on Reconsideration,* 10 FCC Rcd 7393, 7408 (1995).

[42] Industry Data, National Cable & Telecommunications Association, *https://www.ncta.com/industry-data* (last visited May 6, 2014); R.R. Bowker, *Broadcasting & Cable Yearbook 2010,* ''Top 25 Cable/Satellite Operators,'' p. C–2 (data current as of December, 2008).

[43] 47 CFR 76.901(c).

[44] The number of active, registered cable systems comes from the Commission's Cable Operations and Licensing System (COALS) database on Aug. 28, 2013. A cable system is a physical system integrated to a principal headend.

[45] 47 U.S.C. 543(m)(2); *see* 47 CFR 76.901(f) & nn. 1–3.

[46] 47 CFR 76.901(f); *see* Public Notice, *FCC Announces New Subscriber Count for the Definition of Small Cable Operator,* DA 01–158 (Cable Services Bureau, Jan. 24, 2001).

[47] R.R. Bowker, *Broadcasting & Cable Yearbook 2006,* ''Top 25 Cable/Satellite Operators,'' pages A–8 & C–2 (data current as of June 30, 2005); Warren Communications News, *Television & Cable Factbook 2006,* ''Ownership of Cable Systems in the United States,'' pp. D–1805 to D–1857.

[48] The Commission does receive such information on a case-by-case basis if a cable operator appeals a local franchise authority's finding that the operator does not qualify as a small cable operator pursuant to 76.901(f) of the Commission's rules. See 47 CFR 76.909(b).

subscriber's location. DBS, by exception, is now included in the SBA's broad economic census category, Wired Telecommunications Carriers,[49] which was developed for small wireline firms. Under this category, the SBA deems a wireline business to be small if it has 1,500 or fewer employees.[50] To gauge small business prevalence for the DBS service, the Commission relies on data currently available from the U.S. Census for the year 2007. According to that source, there were 3,188 firms that in 2007 were Wired Telecommunications Carriers. Of these, 3,144 operated with less than 1,000 employees, and 44 operated with more than 1,000 employees. However, as to the latter 44 there is no data available that shows how many operated with more than 1,500 employees. Based on this data, the majority of these firms can be considered small.[51] Currently, only two entities provide DBS service, which requires a great investment of capital for operation: DIRECTV and EchoStar Communications Corporation (''EchoStar'') (marketed as the DISH Network).[52] Each currently offers subscription services. DIRECTV [53] and EchoStar [54] each report annual revenues that are in excess of the threshold for a small business. Because DBS service requires significant capital, we believe it is unlikely that a small entity as defined by the SBA would have the financial wherewithal to become a DBS service provider.

186. Cable and Other Subscription Programming. This industry comprises establishments primarily engaged in operating studios and facilities for the broadcasting of programs on a subscription or fee basis. The broadcast programming is typically narrowcast in nature (e.g., limited format, such as news, sports, education, or youth-oriented). These establishments produce programming in their own facilities or acquire programming. The programming material is usually delivered to a third party, such as cable systems or direct-to-home satellite systems, for transmission to viewers.[55] The SBA size standard for this industry establishes as small any company in this category which receives annual receipts of $38.5 million or less.[56] Based on U.S. Census data for 2007, a total of 659 establishments operated for the entire year.[57] Of that 659, 197 operated with annual receipts of $10 million or more. The remaining 462 establishments operated with annual receipts of less than $10 million. Based on this data, the Commission estimates that the majority of establishments operating in this industry are small.

187. Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing. The Census Bureau defines this category as follows: ''This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: Transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment.'' [58] The SBA has developed a small business size standard for Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, which is: All such firms having 750 or fewer employees.[59] According to Census Bureau data for 2007, there were a total of 939 establishments in this category that operated for part or all of the entire year. Of this total, 912 had less than 500 employees and 17 had more than 1000 employees.[60] Thus, under that size standard, the majority of firms can be considered small.

188. Audio and Video Equipment Manufacturing. The SBA has classified the manufacturing of audio and video equipment under in NAICS Codes classification scheme as an industry in which a manufacturer is small if it has fewer than 750 employees.[61] Data contained in the 2007 U.S. Census indicate that 492 establishments operated in that industry for all or part of that year. In that year, 488 establishments had fewer than 500 employees; and only 1 had more than 1000 employees.[62] Thus, under the applicable size standard, a majority of manufacturers of audio and video equipment may be considered small.

189. Wireless Telecommunications Carriers (except satellite). The Census Bureau defines this category as follows: ''This industry comprises establishments engaged in operating and maintaining switching and transmission facilities to provide communications via the airwaves. Establishments in this industry have spectrum licenses and provide services using that spectrum, such as cellular phone services, paging services, wireless Internet access, and wireless video services.'' [63] The appropriate size standard under SBA rules is for the category Wireless Telecommunications Carriers (except Satellite). The size standard for that category is that a business is small if it has 1,500 or fewer employees.[64] For this category, census data for 2007 show that there were 1,383 firms that operated for the entire year.[65] Of this total, 1,368 firms had employment of 999 or fewer employees and 15 had employment of

[49] *See* 13 CFR 121.201 (NAICS code 517110).

[50] *Id.*

[51] *See* U.S. Census Bureau, Table No. EC0751SSSZ5, *Information: Subject Series—Establishment and Firm Size: Employment Size of Firms for the United States: 2007* (NAICS code 517110), *http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2007_US_51SSSZ5.*

[52] *See Annual Assessment of the Status of Competition in the Market for the Delivery of Video Programming,* Fifteenth Annual Report, MB Docket No. 12–203, 28 FCC Rcd 10496, 10507, para. 27 (2013) (''*15th Annual Report*'').

[53] As of June 2012, DIRECTV is the largest DBS operator and the second largest MVPD, serving an estimated 19.8% of MVPD subscribers nationwide. *See 15th Annual Report,* 28 FCC Rcd at 687, Table B–3.

[54] As of June 2012, DISH Network is the second largest DBS operator and the third largest MVPD, serving an estimated 13.01% of MVPD subscribers nationwide. *Id.* As of June 2006, Dominion served fewer than 500,000 subscribers, which may now be receiving ''Sky Angel'' service from DISH Network. *See id.* at 581, para. 76.

[55] U.S. Census Bureau, *2012 NAICS Definitions: 515210 Cable and Other Subscription Programming, http://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=515210&search=2012* (last visited Mar. 6, 2014).

[56] *See* 13 CFR 121.201 (NAICS code 515210).

[57] *See* U.S. Census Bureau, Table No. EC0751SSSZ1, Information: Subject Series—Establishment and Firm Size: Receipts Size of Establishments for the United States: 2007 (NAICS code 515210), *http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2007_US_51SSSZ1.*

[58] U.S. Census Bureau, 2012 NAICS Definitions: 334220 Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, *http://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=334220&search=2012* (last visited Mar. 6, 2014).

[59] 13 CFR 121.201 (NAICS code 334220).

[60] See U.S. Census Bureau, Table No. EC0731SG3, *Manufacturing: Summary Series: General Summary: Industry Statistics for Subsectors and Industries by Employment Size: 2007* (NAICS code 334220), *http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2007_US_31SG3.*

[61] 13 CFR 121.201 (NAICS code 334310).

[62] *See* U.S. Census Bureau, Table No. EC0731SG3, *Manufacturing: Summary Series: General Summary: Industry Statistics for Subsectors and Industries by Employment Size: 2007* (NAICS code 334310), *http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2007_US_31SG3.*

[63] U.S. Census Bureau, *2012 NAICS Definitions: 517210 Wireless Telecommunications Carriers (except Satellite), http://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=517210&search=2012* (last visited Mar. 6, 2014).

[64] 13 CFR 121.201 (NAICS code 517210).

[65] U.S. Census Bureau, Table No. EC0751SSSZ5, *Information: Subject Series—Establishment and Firm Size: Employment Size of Firms for the United States: 2007* (NAICS code 517210), *http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2007_US_51SSSZ5.*

1000 employees or more.[66] Similarly, according to Commission data, 413 carriers reported that they were engaged in the provision of wireless telephony, including cellular service, PCS, and Specialized Mobile Radio (''SMR'') Telephony services.[67] Of these, an estimated 261 have 1,500 or fewer employees and 152 have more than 1,500 employees.[68] Consequently, the Commission estimates that approximately half or more of these firms can be considered small. Thus, using available data, we estimate that the majority of wireless firms can be considered small.

190. Manufacturers of Unlicensed Devices. In the context of this FRFA, manufacturers of Part 15 unlicensed devices that are operated in the UHF–TV band (channels 14–51) for wireless data transfer fall into the category of Radio and Television and Wireless Communications Equipment Manufacturing. The Census Bureau defines this category as follows: ''This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: Transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment.'' [69] The SBA has developed the small business size standard for this category as firms having 750 or fewer employees.[70] According to Census Bureau data for 2007, there were a total of 939 establishments in this category that operated for the entire year.[71] Of this total, 912 had less than 500 employees and 17 had more than 1000 employees. Thus, under that size standard, the majority of firms can be considered small.

191. Personal Radio Services/Wireless Medical Telemetry Service (''WMTS''). Personal radio services provide short-range, low power radio for personal communications, radio signaling, and business communications not provided for in other services. The Personal Radio Services include spectrum licensed under part 95 of our rules.[72] These services include Citizen Band Radio Service (''CB''), General Mobile Radio Service (''GMRS''), Radio Control Radio Service (''R/C''), Family Radio Service (''FRS''), Wireless Medical Telemetry Service (''WMTS''), Medical Implant Communications Service (''MICS''), Low Power Radio Service (''LPRS''), and Multi-Use Radio Service (''MURS'').[73] There are a variety of methods used to license the spectrum in these rule parts, from licensing by rule, to conditioning operation on successful completion of a required test, to site-based licensing, to geographic area licensing. Under the RFA, the Commission is required to make a determination of which small entities are directly affected by the rules adopted. Since all such entities are wireless, we apply the definition of Wireless Telecommunications Carriers (except Satellite), pursuant to which a small entity is defined as employing 1,500 or fewer persons.[74] For this category, census data for 2007 show that there were 1,383 firms that operated for the entire year.[75] Of this total, 1,368 firms had employment of 999 or fewer employees and 15 had employment of 1000 employees or more.[76] Thus under this category and the associated small business size standard, the Commission estimates that the majority of personal radio service and WMTS providers are small entities.

192. However, we note that many of the licensees in these services are individuals, and thus are not small entities. In addition, due to the mostly unlicensed and shared nature of the spectrum utilized in many of these services, the Commission lacks direct information upon which to base a more specific estimation of the number of small entities under an SBA definition that might be directly affected by our action.

193. Motion Picture and Video Production. The Census Bureau defines this category as follows: ''This industry comprises establishments primarily engaged in producing, or producing and distributing motion pictures, videos, television programs, or television commercials.'' [77] The SBA has developed a small business size standard for this category, which is: all such businesses having $30 million dollars or less in annual receipts.[78] Census data for 2007 show that there were 9,478 establishments that operated that year.[79] Of that number, 9,128 had annual receipts of $24,999,999 or less, and 350 had annual receipts ranging from not less than $25,000,000 to $100,000,000 or more.[80] Thus, under this size standard, the majority of such businesses can be considered small entities.

194. Radio Broadcasting. The SBA defines a radio broadcast station as a small business if such station has no more than $38.5 million in annual receipts.[81] Business concerns included in this industry are those ''primarily engaged in broadcasting aural programs by radio to the public.'' [82] According to review of the BIA Publications, Inc. Master Access Radio Analyzer Database as of November 26, 2013, about 11,331 (or about 99.9 percent) of 11,341 commercial radio stations have revenues of $35.5 million or less and thus qualify as small entities under the SBA definition. The Commission notes, however, that, in assessing whether a business concern qualifies as small under the above definition, business (control) affiliations [83] must be included. This estimate, therefore, likely

[66] *Id.* Available census data do not provide a more precise estimate of the number of firms that have employment of 1,500 or fewer employees; the largest category provided is for firms with 1000 employees or more.

[67] *See Trends in Telephone Service* at Table 5.3.

[68] *See id.*

[69] U.S. Census Bureau, *2012 NAICS Definitions: 334220 Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, http://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=334220&search=2012* (last visited Mar. 6, 2014).

[70] 13 CFR 121.201 (NAICS code 334220).

[71] U.S. Census Bureau, Table No. EC0731SG3, *Manufacturing: Summary Series: General Summary: Industry Statistics for Subsectors and Industries by Employment Size: 2007* (NAICS code 334220), *http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2007_US_31SG3.*

[72] 47 CFR part 95.

[73] The Citizens Band Radio Service, General Mobile Radio Service, Radio Control Radio Service, Family Radio Service, Wireless Medical Telemetry Service, Medical Implant Communications Service, Low Power Radio Service, and Multi-Use Radio Service are governed by subpart D, subpart A, subpart C, subpart B, subpart H, subpart I, subpart G, and subpart J, respectively, of part 95 of the Commission's rules. *See generally* 47 CFR part 95.

[74] 13 CFR 121.201 (NAICS Code 517210).

[75] U.S. Census Bureau, Table No. EC0751SSSZ5, *Information: Subject Series—Establishment and Firm Size: Employment Size of Firms for the United States: 2007* (NAICS code 517210), *http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2007_US_51SSSZ5.*

[76] *Id.* Available census data do not provide a more precise estimate of the number of firms that have employment of 1,500 or fewer employees; the largest category provided is for firms with 1000 employees or more.

[77] U.S. Census Bureau, *2012 NAICS Definitions: 512110 Motion Picture and Video Production, http://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=512110&search=2012* (last visited Mar. 6, 2014).

[78] 13 CFR 121.201, 2012 NAICS code 512110.

[79] U.S. Census Bureau, Table No. EC0751SSSZ5, *Information: Subject Series—Establishment and Firm Size: Employment Size of Firms for the United States: 2007* (NAICS code 512110), *http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ECN_2007_US_51SSSZ5.*

[80] *See id.*

[81] 13 CFR 121.201, 2012 NAICS code 515112.

[82] U.S. Census Bureau, *2012 NAICS Definitions: 515112 Radio Broadcasting, http://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=515112&search=2012* (last visited Mar. 6, 2014).

[83] *See* n.14.

overstates the number of small entities that might be affected, because the revenue figure on which it is based does not include or aggregate revenues from affiliated companies.

195. In addition, an element of the definition of ''small business'' is that the entity not be dominant in its field of operation. The Commission is unable at this time to define or quantify the criteria that would establish whether a specific radio station is dominant in its field of operation. Accordingly, the estimate of small businesses to which rules may apply does not exclude any radio station from the definition of a small business on this basis and therefore may be over-inclusive to that extent. Also, as noted, an additional element of the definition of ''small business'' is that the entity must be independently owned and operated. The Commission notes that it is difficult at times to assess these criteria in the context of media entities and the estimates of small businesses to which they apply may be over-inclusive to this extent.

196. Radio, Television, and Other Electronics Stores. The Census Bureau defines this economic census category as follows: ''This U.S. industry comprises: (1) Establishments known as consumer electronics stores primarily engaged in retailing a general line of new consumer-type electronic products such as televisions, computers, and cameras; (2) establishments specializing in retailing a single line of consumer-type electronic products; (3) establishments primarily engaged in retailing these new electronic products in combination with repair and support services; (4) establishments primarily engaged in retailing new prepackaged computer software; and/or (5) establishments primarily engaged in retailing prerecorded audio and video media, such as CDs, DVDs, and tapes.'' [84] The SBA has developed a small business size standard for Electronic Stores, which is: All such firms having $32.5 million or less in annual receipts.[85] According to Census Bureau data for 2007, there were 11,358 firms in this category that operated for the entire year.[86] Of this total, 11,323 firms had annual receipts of under $25 million, and 35 firms had receipts of $25 million or more but less than $50 million.[87] Thus, the majority of firms in this category can be considered small.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

197. *Use of databases.* The NPRM seeks comment on the use of use of databases. Wireless microphone technologies today do not use a database as a mechanism for indicating to the wireless microphone user that particular frequencies in a particular area were available, such as at particular locations that were not being used by other users with priority over the wireless microphone users. White space devices operating in the TV bands must access a database to determine that spectrum is available for their operations and that they would not potentially be interfering with other users at specified locations and times.[88] Would wireless microphone systems potentially benefit from the ability to access to a database? Could requiring use of a database for gaining access to spectrum in a particular band or identifying particular locations and times where they may operate without causing interference to other users in the band help to mitigate or eliminate the concerns of other users in the band that wireless microphone operations might cause harmful interference to these other users? What might be the costs and benefits of developing and using a database, and would these differ depending on the needs of particular types of wireless microphone users?

198. *Use of other technologies that promote opportunities to access additional spectrum.* We seek comment on other technological advancements that could promote greater opportunities for wireless microphones to share use of spectrum in different bands.

199. Are there technological advances that are currently available or contemplated that better enable wireless microphones to adjust dynamically to a particular interference environment, either automatically or through coordination, to promote more efficient use among the wireless microphones or among wireless microphones and other users in the band? For instance, could devices that include sophisticated dynamic power variability capabilities help promote more intensive use of the spectrum resource in a given area? Would these more dynamic capabilities enable wireless microphones to vary or adjust power levels to minimize or eliminate interference to other users in a particular setting, or facilitate more re-use of the available spectrum? We invite comment on whether technological advances along these lines could both facilitate more efficient use of the spectrum while also helping to ensure that they do not cause harmful interference to other users of the spectrum.

200. Are there particular technologies, such as an ''electronic key'' or similar mechanism, that would ensure that a wireless microphone device be able to access and operate only on particular frequencies at particular locations and times, but nowhere else, thus eliminating the potential for harmful interference to other users (such as other users with primary or superior spectrum rights are particularly sensitive to harmful interference) and by so doing provide additional opportunities for wireless microphone operations in bands? [89] Are there other approaches that would effectively limit wireless microphone operation to particular locations, thus protecting other operators from harmful interference? We seek broad comment on the development and use of these types of mechanisms and the tradeoffs or practicalities associated with them. Are there particular scenarios or bands in which use of these mechanisms could provide additional opportunities to access spectrum?

201. *Other technological advances.* Are there other technological advancements that could help to ensure that the various different wireless microphone users' needs are accommodated over the longer term? What are they? Are there actions the Commission should take to promote these developments so that they occur in a timely fashion?

202. In this proceeding, the Commission invites comment on potential revisions to the existing rules for Part 74 wireless microphone (and other LPAS) operations in the spectrum that will remain allocated for TV services following the repacking process. Specifically, we invite comment on revisions to the technical rules for LPAS operations on the VHF

[84] U.S. Census Bureau, *2012 NAICS Definitions, 443142 Electronics,http://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=443142&search=2012* NAICS Search (last visited May 6, 2014).

[85] 13 CFR 121.201, NAICS code 443142.

[86] U.S. Census Bureau, 2007 Economic Census, Subject Series: Retail Trade, Estab & Firm Size: Summary Statistics by Sales Size of Firms for the United States: 2007, NAICS code 443142 (released 2010), *http://www2.census.gov/econ2007/EC/sector44/EC0744SSSZ4.zip* (last visited May 7, 2014). Though the current small business size standard for electronic store receipts is $30 million or less in annual receipts, in 2007 the small business size standard was $9 million or less in annual receipts. In 2007, there were 11,214 firms in this category that operated for the entire year. Of this total, 10,963 firms had annual receipts of under $5 million, and 251 firms had receipts of $5 million or more but less than $10 million. *Id.*

[87] *Id.* An additional 33 firms had annual receipts of $50 million or more.

[88] 47 CFR 15.711(b)(3).

[89] See Section III.C.8, above (discussion of use of an electronic key when accessing the 1.4 GHz band).

band; on permitting licensed LPAS operations on channels in locations closer to the television stations (including within the DTV contour), without the need for coordination, provided that the television signal falls below specified technical thresholds; on adoption of the ETSI emission mask standard for analog and digital wireless microphones; and general comment on other potential revisions concerning licensed LPAS operations in the TV bands.

203. *Consumer Education and Outreach.* We seek comment on the consumer education and outreach efforts that should be employed to educate wireless microphone users, particularly unlicensed users operating in the repurposed 600 MHz band. Our goals are to make information available so users are aware that they must cease operating their wireless microphones on the repurposed 600 MHz Band no later than the end of the transition period (*i.e.,* 39 months after the release of the *Channel Reassignment PN*); to set in motion a process so they are aware of relevant factors concerning the operation of wireless microphones that are currently in use; and to establish a means for users to locate additional spectrum and equipment for their operations. A successful consumer education and outreach campaign will involve the Commission staff working with a broad group of interested entities, including wireless microphone manufacturers, wireless microphones users, and user representatives.

204. Given that a portion of the UHF spectrum that is currently used and available for wireless microphone operations may no longer be available following the incentive auction,[90] we seek comment on how wireless microphone users can be provided access to information on the specific frequencies and the geographic areas of repurposed spectrum that will no longer be available for wireless microphone use at the end of the transition. What specific information should be provided to wireless microphone users to ensure that they know the requirements for operating in the repurposed spectrum during the transition period and the need to exit the band by the end of the transition? Although the *Channel Reassignment PN* will provide information on the spectrum that will be repurposed and no longer available for wireless microphones,[91] we first seek comment on what steps can be taken to provide wireless microphone users with information on the transition prior to the auction. For example, we seek comment on whether explanations could be provided on the Commission's Web site and on the Web sites of manufacturers that would explain the steps required under the Commission's rules to vacate the repurposed 600 MHz Band, and any information on alternative spectrum that is currently available outside of this spectrum, as well any additional spectrum bands that may become available for wireless microphone operations beyond those already provided for in the rules.[92]

205. What other means should be employed to provide wireless microphone users notice of the repurposed spectrum that will be assigned to new wireless licensees, including the specific frequencies in the UHF spectrum and the geographic locations that will no longer be available for wireless microphone operations? We seek comment on whether it would it be beneficial for wireless microphone users to have access to a database that identifies spectrum in the repurposed 600 MHz Band. For example, should some form of online mapping tool be made available to allow users to enter the location and operating frequencies of a wireless microphone and determine whether it operates in the repurposed 600 MHz Band? In the event that a database or similar approach is adopted, we seek comment on who should be responsible for developing and maintaining (hosting) it, including who should be responsible for its cost. Commenters should provide quantitative and qualitative data on costs and benefits of their proposals.

206. Further, should the Commission work with wireless microphone manufacturers to obtain information on models of wireless microphones that the Commission could list on its Web site? For example, this information could include a list all models of wireless microphones sold in the U.S., and all wireless microphone models that operate in the repurposed 600 MHz Band, as well as where on the device or in its product literature the user could look to determine the frequencies on which it is capable of operating.[93] We seek comment on whether making this type of information publically available would help to facilitate a smooth transition from the 600 MHz Band.

207. In addition to steps that may involve manufacturers, we seek comment on what steps other parties associated with the sale and operation of wireless microphones may be able to take to provide users with information relevant to the transition. These other parties may include: Wireless microphone distributors and retailers; parties that lease or manage wireless microphones; trade associations and user groups, including those that have participated in Commission proceedings concerning wireless microphones; organizations that host Web sites and publish information that addresses wireless microphone operations and use or are reasonably expected to have significant numbers of wireless microphone users among their members and readers; and engineering and industry associations or other groups with members that use or operate wireless microphones. Involvement in education and outreach by these parties will be essential, given users' investment in wireless microphone equipment and the upcoming changes regarding wireless microphone use, including the requirement that they vacate the 600 MHz Band. Further, it is important that education and outreach extend to information concerning any newly-allocated spectrum for wireless microphone operations and the potential for users to opt for a suite of wireless microphones operating in different spectrum bands and with different capabilities, depending on the user's specific requirements. We note that wireless microphone users can encompass a wide range of entities, including both licensed and unlicensed users, and parties with differing levels of wireless microphone needs and expertise covering many different applications. Based on these considerations, it is likely that the need for information on the various spectrum bands that will be available for wireless microphone operations, and the conditions specific to each, will be vital. We seek comment on these matters, and on what steps can be taken to assure

[90] *Incentive Auction R&O,* 29 FCC Rcd 6704–05 para. 316.

[91] In addition to initiating the 39-month transition period, the *Channel Reassignment PN* will identify the new channel assignments for full power and Class A television stations that have been reassigned to different channels resulting from the incentive auction and the repacking process. See *Incentive Auction R&O,* 29 FCC Rcd at 6782 para. 525.

[92] Elsewhere in the *NPRM,* we seek comment on whether a number of other spectrum bands should be allocated for wireless microphone use. See Sections III.C.5, III.C.8, and III C.10, above.

[93] As part of the transition of wireless microphones from the 700 MHz band, the Commission made available a list of many wireless microphones that operated on the 700 MHz band, as provided by a number of manufacturers. *See http://www.fcc.gov/encyclopedia/wireless-microphones-manufacturers-equipment-list.* Wireless microphone users could look at this information and determine if their devices were 700 MHz wireless microphones and thus could not be used after the transition deadline, or given information to contact the Commission for additional assistance if the manufacturer of their devices was not listed.

that the information to educate users on the transition will be commensurate with the appropriate needs and levels of expertise of all users.

208. The Commission seeks comment on what additional information we should make available for wireless microphone users, including Commission-issued consumer ''fact sheets'' and ''frequently asked questions'' (''FAQ's'') which would address, among other matters, information on operation in the 600 MHz Band, the reason for the need to operate on frequencies outside of that band following the transition, the availability of other frequency bands for wireless microphone use, and the need to comply with Commission rules. We further seek comment on how to release or distribute these materials in order to most effectively and efficiently reach the target audience of wireless microphone users.

209. The Commission seeks comment on the specific actions that wireless microphone manufacturers, distributors, retailers and other entities comprising the wireless microphone community should take to inform the wide range of wireless microphone users about the ongoing developments concerning wireless microphone use—particularly the need to vacate the repurposed 600 MHz Band, the timetable for doing so, and the conditions for operating in the band during the transition period. We seek comment on whether and to what extent these entities can make this type of information available, including, as appropriate, by posting it on their Web sites, including it in all sales literature, or taking other steps to inform current or potential wireless microphone users of matters concerning the operation of their devices. We also seek comment on whether manufacturers would consider rebates, equipment trade-ins, or similar programs to facilitate the transition, and what effect the 39-month transition period would have on a decision to implement such a program. In addition, we seek comment on the economic costs and benefits of adopting consumer outreach measures.

210. *Disclosure Requirements.* The Commission proposes to revise our point-of-sale disclosure requirement that the Commission adopted in the *Wireless Microphone Report and Order* in order to provide information to wireless microphone users that may have to purchase or lease new equipment so that they can vacate the repurposed 600 MHz Band. In the *TV Bands Wireless Microphones Report and Order,* the Commission adopted a point-of-sale requirement to help assure that consumers were informed of their rights and obligations if they chose to operate wireless microphones and other low power auxiliary stations in the core TV bands (defined in the rule as channels 2–51, excluding channel 37).[94] Specifically, the Commission adopted a requirement for manufacturers and distributors of wireless microphones that operate in the core TV bands to provide a written disclosure informing consumers of the requirements for operating devices in that spectrum and to display the disclosure at the point of sale and on their Web sites.[95] The Commission also provided that persons who manufacture or market wireless microphones destined for export and capable of operating in the 700 MHz Band must include labeling stating that the devices cannot be used in the United States.[96]

211. We propose to revise the existing point-of-sale disclosure requirement in order to facilitate a smoother transition in which wireless microphone users are informed of the need to vacate the repurposed 600 MHz Band, while fully understanding their rights and obligations during the transition period and at the end of the transition period. With regard to sales of wireless microphones that are capable of operating in repurposed spectrum, we propose to require that such sales include point-of-sale disclosures that inform buyers that they are buying a microphone that cannot be used in certain frequencies following the transition. We also seek comment on how point-of-sale disclosures could be designed to effectively address any ban on manufacturing and marketing of wireless microphones that are capable of operating in the repurposed 600 MHz Band.[97] We propose that the revised point-of-sale disclosures should direct buyers to the manufacturer's toll free telephone number or the manufacturer's Web site where the buyer can obtain more detailed information on the extent to which the microphone may be affected by repurposing of 600 MHz Band. Should we retain the existing language in the point-of-sale disclosure requirement that includes the Commission's toll free number and the Commission's Web site where users can obtain additional information on the operation of wireless microphones during the transition period and after the transition period? What other information should be included in the disclosure?

212. We propose that the effective date for any disclosure requirement, including a point-of-sale requirement, which we may adopt in connection with this or a related proceeding, shall be 12 months after the release of the *Channel Reassignment PN*—which will mark the effective date of channel reassignments based on the repacking process, specify any specific channel assignments for television stations that will continue to broadcast, and start the clock running on the post-auction transition period—or should some other date be used instead? We seek comment on the particular factors that should enter into this determination. We note that in adopting the current disclosure requirement, the Commission stated that it would remain in effect until the effective date of the final rules adopted in response to the *2010 TV Bands Wireless Microphones FNPRM.*[98]

[94] *See TV Bands Wireless Microphones R&O,* 25 FCC Rcd at 687–691 paras. 91–106.

[95] *See TV Bands Wireless Microphone R&O,* 25 FCC Rcd at 688–689 para. 96; 47 CFR 15.216. The required disclosure states: ''Most users do not need a license to operate this wireless microphone system. Nevertheless, operating this microphone system without a license is subject to certain restrictions: The system may not cause harmful interference; it must operate at a low power level (not in excess of 50 milliwatts); and it has no protection from interference received from any other device. Purchasers should also be aware that the FCC is currently evaluating use of wireless microphone systems, and these rules are subject to change. For more information, call the FCC at 1–888–CALL–FCC (TTY: 1–888–TELL–FCC) or visit the FCC's wireless microphone Web site at *http://www.fcc.gov/cgb/wirelessmicrophones.*'' *See* 47 CFR 15.216, Appendix. The Commission noted that manufacturers and distributors could satisfy the disclosure requirement in more than one way, including by displaying the text in a prominent manner on the product box via a label or sticker; displaying the text immediately adjacent to the device in a manner clearly associated with the device; and, for wireless microphones offered online or via direct mail or catalog, displaying the text in close proximity to the images and descriptions of each wireless microphone. *See TV Bands Wireless Microphones Report and Order*, 25 FCC Rcd at 689 para. 100.

[96] *See TV Bands Wireless Microphones R&O*, 25 FCC Rcd at 666 para. 43; *see also* 47 CFR 74.851(h). In the *TV Bands Wireless Microphones FNPRM*, the Commission also sought comment on whether to adopt labeling and other marketing restrictions to help ensure that devices certificated as low power auxiliary stations under part 74 were marketed only to parties eligible for a part 74 license. In particular, the Commission sought comment on whether to require manufacturers to direct marketing of part 74-certificated devices only to parties eligible to operate them; whether to require manufacturers to track the parties to whom their products are marketed; whether to require manufacturers to provide a label visible at the time of purchase or instructions in the user manual advising purchasers of the requirement to obtain a license; and whether to prohibit manufacturers and distributors from selling devices certificated under Part 74 unless the sale is to a party that has committed in writing that it is a bona fide reseller or eligible for a license under Part 74. *See TV Bands Wireless Microphones FNPRM*, 25 FCC Rcd at 701–702 paras. 141–144.

[97] *See infra* Section III.C.1.b(iii).

[98] *See TV Bands Wireless Microphones FNPRM,* 25 FCC Rcd at 689 para. 100.

E. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered

213. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): (1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance or reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage of the rule, or any part thereof, for small entities.[99]

214. In the *NPRM* we request comment on whether, apart from establishing such a TV signal threshold, we should adopt any other safeguards to ensure that licensed wireless microphone operators comply with this threshold and do not otherwise cause harmful interference to TV reception. We note at the outset that because we would limit these types of operations to licensed wireless microphone users, we would expect such users to have the requisite wireless microphone systems, as well as technical and operational abilities, to be able to determine the level of the co-channel TV signals at a given location, and thus would be able to comply with any threshold rule that we adopted. Is this a reasonable expectation? To what extent would a wireless microphone operations require a low TV signal to be able operate effectively on a co-channel basis? Should we require licensed wireless microphone users to register their co-channel operations in the TV bands databases, which could provide information to any television licensee concerned about possible harmful interference? Are there other actions we should take?

215. As an alternative approach, the Commission seeks comment on whether it should permit co-channel licensed wireless microphone operations in indoor venues, such as in theaters or music auditoriums. Could an appropriate approach towards indoor operations be developed that would also effectively preclude harmful interference to any potential TV viewers at indoor locations? For instance, could certain locations be readily identified where wireless microphone operations can be permitted, provided of course that they are operated consistent with applicable technical requirements, including power limits and out-of-bound emissions requirements? Or, considering that in order to operate effectively wireless microphones need access to channels that are sufficiently interference-free, is it reasonable to expect that co-channel wireless microphone operations would only take place in indoor locations on channels with relatively low or effectively non-existent TV signal, and thus conclude that such operations would not be likely to effectively harm TV viewers? Some commenters in the incentive auction proceeding suggested that such operations may already take place without incident.[100] As we explore this approach, the Commission seeks comment on the benefits or downsides of allowing licensed wireless microphone operations at indoor locations, or at specified types of indoor locations. We ask that commenters provide any technical analysis bases for their recommendations.

216. We also invite comment on other approaches that we should take on expanding wireless microphone operations on a co-channel basis closer to television station operations. Again, commenters proposing any alternative approaches should provide technical analyses to support their approaches, and discuss the benefits of such an approach and how their approaches would not cause harmful interference to channels that would be used for wireless microphone operations.

F. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rule

217. None.

Congressional Review Act

218. The Commission will send a copy of the Notice of Proposed Rulemaking to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

Ordering Clauses

219. Pursuant to sections 1, 4(i), 7(a), 301, 303(f), 303(g), 303(r), 307(e) and 332 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 157(a), 301, 303(f), 303(g), 303(r), 307(e), and 332, the Notice of Proposed Rulemaking *is adopted.*

220. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of the Notice of Proposed Rule Making, including the Initial Regulatory Flexibility Analysis to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR part 74

Communications equipment, Education, Reporting and recordkeeping requirements.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR part 74 to read as follows:

PART 74—EXPERIMENTAL RADIO, AUXILIARY, SPECIAL BROADCAST AND OTHER PROGRAM DISTRIBUTIONAL SERVICES

Subpart H—Low Power Auxiliary Stations

■ 1. The authority citation for part 74 continues to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, 307, 309, 336 and 554.

■ 2. Section 74.801 is amended by adding the definition for ''Repurposed 600 MHz Band'' in alphabetical order to read as follows:

§ 74.801 Definitions.

* * * * *

Repurposed 600 MHz Band. Frequencies that will be reallocated and reassigned for part 27 600 MHz Band services as determined by the outcome of the auction conducted pursuant to *Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions, Report and Order,* GN Docket No. 12–268 (FCC 14–50), 29 FCC 6567 (2014).

* * * * *

■ 3. Section 74.832 is amended by revising paragraph (d) to read as follows:

§ 74.832 Licensing Requirements and procedures.

* * * * *

(d) Cable television operations, motion picture and television program producers, large venue owners or operators, and professional sound companies may be authorized to operate low power auxiliary stations in the bands allocated for TV broadcasting and in the 944–952 MHz band.

* * * * *

■ 4. Section 74.851 is amended by revising the section heading and paragraph (i), and adding paragraphs (j) through (l) to read as follows:

[99] *See* 5 U.S.C. 603(c).

[100] *See, e.g.,* Sennheiser Reply Comments (Docket No. 12–268) at 18.

§ 74.851 Certification of equipment; prohibition on manufacture, import, sale, lease, offer for sale or lease, or shipment of devices that operate in the 700 MHz Band or the 600 MHz Band; labeling for 700 MHz or 600 MHz band equipment destined for non-U.S. markets; disclosures.

* * * * *

(i) Effective nine months after the release of the Commission's Channel Reassignment Public Notice issued pursuant to *Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions,* Report and Order, GN Docket No. 12–268 (FCC 14–50), 29 FCC 6567 (2014), certification may no longer be obtained for low power auxiliary stations or wireless video assist devices that are capable of operating in the repurposed 600 MHz band as defined in § 74.801.

(j) Effective eighteen months after the release of the Commission's Channel Reassignment Public Notice issued pursuant to *Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions,* Report and Order, GN Docket No. 12–268 (FCC 14–50), 29 FCC 6567 (2014), no person shall manufacture, import, sell, lease, offer for sale or lease, or ship low power auxiliary stations or wireless video assist devices that are capable of operating in the repurposed 600 MHz band as defined in § 74.801. This prohibition does not apply to devices manufactured solely for export.

(k) Effective eighteen months after the release of the Commission's Channel Reassignment Public Notice issued pursuant to *Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions,* Report and Order, GN Docket No. 12–268 (FCC 14–50), 29 FCC 6567 (2014), any person who manufactures, sells, leases, or offers for sale or lease low power auxiliary stations or wireless video assist devices that are destined for non-U.S. markets and that are capable of operating in the repurposed 600 MHz band as defined in § 74.801, shall include labeling and make clear in all sales, marketing, and packaging materials, including online materials, relating to such devices that the devices cannot be operated in the U.S.

(l) Any person, whether such person is a wholesaler or a retailer, who manufactures, sells, leases, or offers for sale or lease low power auxiliary stations or wireless video assist devices that operate in the repurposed 600 MHz band is subject to the disclosure requirements in § 15.216 of this chapter.

■ 5. Section 74.861 is amended by adding paragraphs (d)(4) and (e)(7) to read as follows:

§ 74.861 Technical Requirements.

* * * * *

(d) * * *

(4) Effective as of [date of publication of final rule], emissions within the band from one megahertz below to one megahertz above the carrier frequency shall comply with the emission mask in Section 8.3 of ETSI EN 300 422–1, *Electromagnetic compatibility and Radio spectrum Matters (ERM); Wireless microphones in the 25 MHz to 3 GHz frequency range; part 1: Technical characteristics and methods of measurement.*

* * * * *

(e) * * *

(7) Effective as of [date of publication of final rule], emissions within the band from one megahertz below to one megahertz above the carrier frequency shall comply with the emission mask in Section 8.3 of ETSI EN 300 422–1, *Electromagnetic compatibility and Radio spectrum Matters (ERM); Wireless microphones in the 25 MHz to 3 GHz frequency range; part 1: Technical characteristics and methods of measurement.*

* * * * *

[FR Doc. 2014–26675 Filed 11–20–14; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 223

RIN 0648–XA984

Endangered and Threatened Species; Proposed Listing Determinations for Nassau Grouper; Public Hearing

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

ACTION: Notice of public hearing.

SUMMARY: We (NMFS) will hold a public hearing in St. Thomas, U.S. Virgin Islands, in December 2014 for the purpose of accepting public comments on the proposal to list the Nassau grouper (*Epinephelus striatus*) as threatened under the Endangered Species Act of 1973, as amended (ESA).

DATES: The meeting will be held on December 9, 2014, at 7 p.m. Atlantic Standard Time.

ADDRESSES: The meeting will be held at the Marriott Frenchmans Reef Hotel, 5 Estate Bakkeroe, St. Thomas, U.S. Virgin Islands. Information about the proposed listing of the Nassau grouper under the ESA is available at: *http://sero.nmfs.noaa.gov/protected_resources/listing_petitions/species_esa_consideration/index.html.*

Comments, identified by NOAA–NMFS–2014–0101, may also be submitted by any of the following methods:

- *Electronic Submissions:* Submit all electronic comments via the Federal eRulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2014-0101,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Facsimile (fax*): 727–824–5309.
- *Mail:* NMFS, Southeast Regional Office, 263 13th Avenue South, St. Petersburg, FL 33701.
- *Hand delivery:* You may hand deliver written information to our office during normal business hours at the street address given above.

FOR FURTHER INFORMATION CONTACT: Jason Rueter, NMFS, Southeast Regional Office (727) 824–5350; or Lisa Manning, NMFS, Office of Protected Resources (301) 427–8466.

SUPPLEMENTARY INFORMATION:

Background

On September 2, 2014, we published a proposed rule to list the Nassau grouper (*Epinephelus striatus*) as threatened under the ESA (79 FR 51929). While the species still occupies its historical range, spawning aggregations have been reduced in size and number due to fishing pressure. The lack of adequate management measures to protect these aggregations increases the extinction risk of Nassau grouper. Based on these considerations, described in more detail in the proposed rule (79 FR 51929; September 2, 2014), we concluded that the Nassau grouper is not currently in danger of extinction throughout all or a significant portion of its range, but is likely to become so within the foreseeable future.

We are currently soliciting relevant information that may inform the final listing and designation of critical habitat. In particular we seek comments containing: (1) Information concerning the location(s) and status of any spawning aggregations of the species; and (2) Information concerning the threats to the species; and (3) Efforts being made to protect the species throughout its current range. See **ADDRESSES** section above for information on how to submit comments. The public comment period on the proposed rule is open until December 31, 2014.

Public Hearing

We will convene a public hearing to provide background information and accept public comments on the proposed listing of the Nassau grouper under the ESA. We will accept both oral and written comments regarding the proposed listing decision during the meeting.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Jason Reuter, (727) 824–5350, at least 5 working days prior to the meeting date.

Authority: 16 U.S.C. 1531 *et seq.*

Dated: November 17, 2014.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2014–27651 Filed 11–20–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 140728622–4622–01]

RIN 0648–BE44

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Red Snapper Management Measures

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to implement management measures described in a framework action to the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP), as prepared by the Gulf of Mexico Fishery Management Council (Council). If implemented, this rule would revise the recreational accountability measures (AMs) and establish a recreational annual catch target (ACT) for red snapper in the exclusive economic zone (EEZ) of the Gulf of Mexico (Gulf). The purpose of this proposed rule is to help achieve optimum yield (OY) for the Gulf red snapper resource and better ensure red snapper recreational landings do not exceed the recreational quota established in the rebuilding plan, in accordance with sections 303(a)(15) and 407(d) of the Magnuson-Stevens Act (16 U.S.C. 1853(a)(15); 16 U.S.C. 1883(d)).

DATES: Written comments must be received on or before December 22, 2014.

ADDRESSES: You may submit comments on the proposed rule, identified by ''NOAA–NMFS–2014–0120'' by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2014-0120,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Peter Hood, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

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). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

Electronic copies of the framework action, which includes an environmental assessment, a regulatory impact review, and a Regulatory Flexibility Act analysis may be obtained from the Southeast Regional Office Web site at *http://sero.nmfs.noaa.gov/sustainable_fisheries/gulf_fisheries/reef_fish/index.html.*

FOR FURTHER INFORMATION CONTACT: Peter Hood, Southeast Regional Office, NMFS, telephone 727–824–5305; email: *Peter.Hood@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS and the Council manage the Gulf reef fish fishery under the FMP. The Council prepared the FMP and NMFS implements the FMP through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

Background

In 2013, the most recent Southeast Data, Assessment, and Review (SEDAR) benchmark assessment for Gulf red snapper (SEDAR 31), determined that the red snapper stock in the Gulf is no longer undergoing overfishing. However, it remains overfished and is in the 14th year of a 31-year rebuilding plan that began in 2001 and that will remain in place through 2032. Beginning in the 2008 fishing year, following a substantial reduction in the quota in Amendment 27 to the FMP (73 FR 5117, January 29, 2008), NMFS began projecting the season length of the recreational season on an annual basis based on a June 1 start date. However, due to difficulties in monitoring the recreational harvest and projecting the recreational season length, recreational quota overages have occurred regularly even though the recreational quota has been increasing annually since 2010.

The Magnuson-Stevens Act requires the use of annual catch limits (ACLs) and AMs to end and prevent overfishing. For red snapper, NMFS determined the existing commercial and recreational quotas are functionally equivalent to sector ACLs, and the sum of the quotas is functionally equivalent to the stock ACL. Additionally, the commercial individual fishing quota (IFQ) program serves as an AM for the commercial sector. The recreational AM is currently an in-season closure based on annual projections of the recreational season length.

The current recreational quota, implemented through a 2013 framework amendment (78 FR 57318, September 18, 2013), is 5.390 million lb (2.445 million kg), round weight. The red snapper recreational season begins on June 1, each year. NMFS determines the length of the red snapper recreational season in advance of June 1, and announces the closure date in the **Federal Register**. Previously, this closure was based on projections of when the recreational quota would be caught, but for 2014, projections were based on an ACT that is 20 percent below the quota; this modification was implemented through an emergency rule (79 FR 27768, May 15, 2014).

In September 2013, individual commercial fishermen and two commercial fishing interest groups filed a lawsuit challenging the rules implementing red snapper quotas for the 2013 fishing year and setting the 2013 recreational red snapper fishing season. In March 2014, the Court ruled in favor of the plaintiffs (*Guindon* v. *Pritzker, 2014 WL 1274076; D.D.C. Mar. 26, 2014*), finding in pertinent part that NMFS failed to require adequate AMs to prohibit the retention of fish after the recreational quota had been harvested and address any overages.

To address the Court's decision and reduce the probability that the recreational sector would exceed its quota, the Council requested and NMFS issued an emergency rule for the red snapper recreational sector (79 FR 27768, May 15, 2014). The emergency rule implemented an AM that based the season length on an annual catch target (ACT) that was set 20 percent below the recreational quota. Although the emergency rule established a recreational AM for 2014, permanent recreational AMs are still needed for the 2015 and subsequent fishing years.

Management Measures Contained in This Proposed Rule

If implemented, this proposed rule would establish a red snapper recreational ACT and revise the red snapper recreational AMs to support management efforts to maintain landings within the recreational quota and to mitigate any recreational quota overages should they occur.

Red Snapper Recreational ACT and Season Length

This proposed rule would establish a red snapper recreational ACT by applying a buffer to the recreational quota that is based on the Council's ACL/ACT control rule developed in the Generic ACL/Amendment (76 FR 82044, December 29, 2011). The ACL/ACT control rule establishes a process for determining the appropriate target catch levels that account for management uncertainty in maintaining catches at or below the ACL. The control rule is intended to be applied separately to the recreational and commercial sectors because each sector has different levels of management uncertainty. The control rule recommends no buffer be applied to the quota for the red snapper commercial sector because the sector is managed by an IFQ program, has accurate landings data, and has not exceeded its quota in the last 7 years of the IFQ program being in effect. For the recreational sector, the control rule recommends applying a 20 percent buffer to the quota primarily because of the recreational quota overages in 3 of the last 4 years. Applying the 20 percent buffer to the quota results in an ACT of 4.312 million pounds.

This proposed rule would also revise the procedure for determining the recreational season length (closure date). Beginning with the 2015 fishing year, the red snapper recreational season closure date would be based on the recreational ACT instead of the recreational quota. Using the ACT to set the season length is an in-season AM that reduces the probability of exceeding the recreational quota during a fishing year from 50 percent to 15 percent.

Red Snapper Recreational Post-Season AM

This rule would revise the recreational AMs to also include a quota overage adjustment (payback) should the recreational quota be exceeded while the red snapper stock is overfished. If red snapper are overfished and the recreational quota is exceeded, then in the year following the overage, the recreational quota would be reduced by the amount of the recreational quota overage in the prior fishing year, unless the best scientific information available determines that a greater, lesser, or no overage adjustment is necessary. The recreational ACT would also be reduced to maintain the 20 percent buffer between the ACT and the adjusted quota. This post-season AM is consistent with the National Standard 1 guidelines for stocks that are in a rebuilding plan, as is the case for Gulf red snapper.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this proposed rule is consistent with the FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

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

NMFS prepared an Initial Regulatory Flexibility Analysis (IRFA), as required by section 603 of the Regulatory Flexibility Act, for this proposed rule. The IRFA describes the economic impact this rule, if adopted, would have on small entities. A description of the action, why it is being considered, the objectives of, and legal basis for this action are contained at the beginning of this section in the preamble and in the SUMMARY section of the preamble. A copy of the full analysis is available from NMFS (see **ADDRESSES**). A summary of the IRFA follows.

The Magnuson-Stevens Act provides the statutory basis for this rule. No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, no new reporting, record-keeping, or other compliance requirements are introduced by this rule. Accordingly, this rule does not implicate the Paperwork Reduction Act.

This rule, if implemented, would be expected to directly affect federally permitted for-hire vessels operating in the Gulf reef fish fishery. The for-hire sector is comprised of charter boats and headboats (party boats). Although charter boats tend to be smaller in length, on average, than headboats, the key distinction between the two types of operations is how the fee is determined. On a charter boat trip, the fee charged is for the entire vessel, regardless of how many passengers are carried, whereas the fee charged for a headboat trip is paid per individual angler.

A Federal Gulf charter/headboat permit has been required for reef fish since 1996 and the sector currently operates under a limited access permit system. In 2013, there were 1,190 valid (non-expired) or renewable Gulf of Mexico Charter/Headboat Reef Fish Permits. A renewable permit is an expired permit that may not be actively fished, but is renewable for up to 1 year after expiration. Although the for-hire permit application collects information on the primary method of operation, the permit itself does not identify the federally permitted vessel as either a headboat or a charter boat. Operation as either a headboat or charter boat is not restricted by the Federal permitting regulations, and vessels may operate in both capacities. However, only federally permitted headboats are required to submit harvest and effort information to NMFS' Headboat Survey (HBS). Participation in the HBS is based on determination by the NMFS Southeast Fisheries Science Center (SEFSC) that the vessel primarily operates as a headboat. In 2013, seventy Gulf vessels were registered in the HBS. As a result, 1,120 of the vessels with a valid or renewable reef fish charter/headboat permit are expected to operate as charter boats. The average charter boat is estimated to earn approximately $83,000 (2013 dollars) in gross annual revenue and the average headboat is estimated to earn approximately $251,000 (2013 dollars) in gross annual revenue.

The Small Business Administration established size criteria for all major industry sectors in the U.S. including fish harvesters and for-hire operations. A business involved in finfish harvesting is classified as a small business if independently owned and operated, is not dominant in its field of operation (including its affiliates), and its combined annual receipts are not in excess of $20.5 million (NAICS code 114111, finfish fishing) for all of its affiliated operations worldwide. For for-hire vessels, all qualifiers apply except that the annual receipts threshold is $7.5 million (NAICS code 487210, recreational industries).

Based on the revenue figures above, all for-hire vessels expected to be

directly affected by this rule are determined for the purpose of this analysis to be small business entities.

Because all entities expected to be affected by this rule are small entities, NMFS has determined that this rule would affect a substantial number of small entities. Moreover, the issue of disproportionate effects on small versus large entities does not arise in the present case.

Establishing an ACT, which serves as the basis for estimating the length of the recreational red snapper fishing season, is expected to reduce net operating revenues (the return used to pay all labor wages, returns to capital, and owner profits) of all Gulf reef fish for-hire vessels (charter and headboats) by a combined total of approximately $2.286 million (2013 dollars) in the first year this rule is implemented. If there are no recreational quota overages, this amount will be the annual net operating revenue loss to the for-hire vessels. If recreational quota overages occur in a fishing year, and red snapper are overfished, net operating revenues would further decrease in the following fishing year with the application of 100 percent of the recreational ACL overage reduction from the following year's quota. In effect, establishing a payback provision would tend to increase the potential losses in net operating revenue to the for-hire vessels.

An important feature associated with the payback provision is the uncertainty of the occurrence and level of overages. Under the proposed buffer of 20 percent for deriving the ACT from the recreational ACL, the probability of exceeding the quota is estimated at 15 percent. At this probability level, the occurrence of an overage is relatively low. However, should an overage occur, the overage level could be insignificant or could be substantial. If the ACL overage is low, the net operating revenue loss to the for-hire vessels would be approximately equivalent to the amount estimated above ($2.286 million). If the ACL overage is substantial, it could result in setting the ACT at zero the following year. In this case, net operating revenue loss to the for-hire vessels could be relatively substantial, with some unknown number of for-hire businesses possibly exiting the industry as a result of revenue loss. The year after that overage adjustment, however, the recreational ACL and the corresponding ACT would be restored as there would be no overages in the previous year if the ACT had been set at zero. Assuming no increases in the recreational red snapper quota, for-hire vessels would continue to lose the amount of net operating revenue estimated above. A recreational quota increase would alleviate some of the losses to the for-hire vessels.

Given the uncertainty discussed above, it cannot be ascertained whether the effects of the rule on the net operating revenues of for-hire vessels would be significant. The public, therefore, is encouraged to address this issue during the public comment period.

The following discussion analyzes the alternatives that were not selected as preferred by the Council. Five alternatives, including the preferred alternative (as fully described in the preamble), were considered for setting a red snapper recreational ACT. The first alternative, the no action alternative, would not establish an ACT. This alternative is associated with the highest probability of exceeding the recreational quota and so would not address the need to better control the recreational harvest to the sector's quota. The other three alternatives would establish an ACT by applying a buffer of 30 percent, 40 percent, or 60 percent to the quota. Relative to the preferred alternative, each of these three alternatives would result in a lower ACT and therefore greater loss in net operating revenues for the for-hire component of the recreational sector.

Three alternatives, including the preferred alternative (as fully described in the preamble), were considered for establishing a payback provision in case of recreational ACL overages. It is noted that the payback provision only applies when red snapper are overfished. The first alternative, the no action alternative, would not establish a payback provision. This alternative would not address the need to mitigate for overages that may negatively impact the rebuilding plan. The second alternative would establish a 100 percent recreational ACL payback provision, similar to the preferred alternative, and in addition would further reduce the adjusted ACT in the following season by 100 percent, 50 percent, or 30 percent of the quota overage. The adjusted ACT is derived by applying the 20 percent buffer to the ACL after the recreational ACL is reduced by the amount of overage. This alternative, together with any of its additional options to further reduce the following season's overage adjusted ACT, would be expected to result in higher net operating revenue losses for the for-hire sector.

List of Subjects in 50 CFR Part 622

Fisheries, Fishing, Gulf, Quotas, Red snapper.

Dated: November 18, 2014.

Eileen Sobeck,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is proposed to be amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

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

■ 2. In § 622.41, paragraph (q) is added to read as follows:

§ 622.41 Annual catch limits (ACLs), annual catch targets (ACTs), and accountability measures (AMs).

* * * * *

(q) *Red snapper*—(1) *Commercial sector.* [Reserved]

(2) *Recreational sector.* (i) The AA will determine the length of the red snapper recreational fishing season based on when recreational landings are projected to reach the recreational ACT specified in paragraph (q)(2)(iii) of this section, and announce the closure date in the **Federal Register**. This will serve as an in-season accountability measure. On and after the effective date of the recreational closure notification, the bag and possession limit for red snapper is zero.

(ii) In addition to the measures specified in paragraph (q)(2)(i) of this section, if red snapper recreational landings, as estimated by the SRD, exceed the applicable quota specified in § 622.39(a)(2)(i), and red snapper are overfished, based on the most recent Status of U.S. Fisheries Report to Congress, the AA will file a notification with the Office of the Federal Register to reduce the recreational quota by the amount of the quota overage in the prior fishing year, and reduce the recreational ACT specified in paragraph (q)(2)(iii) of this section (based on the buffer between the ACT and the quota specified in the FMP), unless the best scientific information available determines that a greater, lesser, or no overage adjustment is necessary.

(iii) The recreational ACT for red snapper is 4.312 million lb (1.956 million kg), round weight.

[FR Doc. 2014–27648 Filed 11–20–14; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 79, No. 225
Friday, November 21, 2014

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

Farm Service Agency

Information Collection; Direct Loan Servicing—Special

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 of a currently approved information collection that supports 7 CFR part 766, Direct Loan Servicing—Special programs. The information is used in eligibility and feasibility determinations on borrower requests for disaster set-aside, primary loan servicing, buyout at market value, and homestead protection, as well as liquidation of security.

DATES: We will consider comments that we receive by January 20, 2015.

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 eRulemaking Portal:* Go to *www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Tamara L. Wilson, Senior Loan Officer, USDA/FSA/FLP, STOP 0523, 1400 Independence Avenue SW., Washington, DC 20250–0503.

You may also send comments to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. Copies of the information collection may be requested by contacting Tamara L. Wilson at the above address.

FOR FURTHER INFORMATION CONTACT: Tamara L. Wilson, (202) 690–4012.

SUPPLEMENTARY INFORMATION:

Title: Farm Loan Programs Direct Loan Servicing—Special.

OMB Number: 0560–0233.

Expiration Date: 06/30/2015.

Type of Request: Extension.

Abstract: FSA's Farm Loan Programs provide loans to family farmers to purchase real estate and equipment and finance agricultural production. Direct Loan Servicing—Special, found at 7 CFR part 766, provides the requirements for servicing financially distressed and delinquent direct loan borrowers. FSA's loan servicing options include disaster set-aside, primary loan servicing (including reamortization, rescheduling, deferral, write down and conservation contracts), buyout at market value, and homestead protection. FSA also services borrowers who file bankruptcy or liquidate security when available servicing options are not sufficient to produce a feasible plan. The information collections contained in the regulation are necessary to evaluate a borrower's request for consideration of the special servicing actions.

The formula used to calculate the total burden hour is estimated average time per responses hours times total annual responses.

Estimate of Respondent Burden: Public reporting burden for this information collection is estimated to average 0.58 hours per response. The average travel time, which is included in the total burden, is estimated to be 1 hour per respondent.

Respondents: Individuals or households, businesses or other for profit farms.

Estimated Annual Number of Respondents: 14,934.

Estimated Number of Reponses per Respondent: 1.9.

Estimated Total Annual Responses: 27,923.

Estimated Average Time per Response: 0.58.

Estimated Total Annual Burden on Respondents: 15,858.

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 the 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;

(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.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission for Office of Management and Budget approval.

Signed on November 13, 2014.

Candance Thompson,

Acting Administrator, Farm Service Agency.

[FR Doc. 2014–27434 Filed 11–20–14; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: International Trade Administration (ITA).

Title: Information for Self-Certification under FAQ 6 of the United States (U.S.)—European Union (EU) Safe Harbor Framework and United States (U.S.)—Switzerland (Swiss) Safe Harbor Framework.

OMB Control Number: 0625–0239.

Form Number(s): ITA–4149P.

Type of Request: Regular submission (extension of a currently approved information collection).

Burden Hours: 520.

Number of Respondents: 780.

Average Hours per Response: 40 minutes.

Needs and Uses: In order to ensure continued flows of personal data to the United States from the European Union (EU) and Switzerland, where the national data protection regimes restrict transfers of such data to countries not recognized as providing ''adequate'' privacy protection, the U.S. Department of Commerce (DOC) developed similar,

but separate arrangements with the European Commission and the Federal Data Protection and Information Commissioner of Switzerland (Swiss FDPIC) to provide eligible U.S. organizations with a streamlined means of complying with the relevant EU and Swiss data protection requirements. The complete set of documents and additional guidance materials concerning the U.S.-EU Safe Harbor Framework and the U.S.-Swiss Safe Harbor Framework may be found at *http://export.gov/safeharbor.*

The decision by a U.S. organization to self-certify its compliance with one or both of the Safe Harbor Frameworks is entirely voluntary; however, once made, the organization must comply and publicly declare that it does so. To be assured of Safe Harbor benefits, an organization must reaffirm its self-certification annually to the DOC. Organizations that have self-certified, appear on the relevant public Safe Harbor List(s) maintained by the DOC, and have not allowed their certification status to lapse are presumed to provide ''adequate'' data protection in accordance with EU and Swiss data protection requirements. An organization's self-certification and appearance on the public Safe Harbor List(s) constitute an enforceable representation to the DOC and the public. Any public misrepresentation concerning an organization's participation in the Safe Harbor or compliance with one or both of the Safe Harbor Frameworks may be actionable by the Federal Trade Commission (FTC) or other relevant government body.

The public U.S.-EU Safe Harbor List and the U.S.-Swiss Safe Harbor List, which are necessary to make the Safe Harbor Frameworks operational, and were a key demand of the European Commission and the Swiss FDPIC in agreeing that compliance with the Safe Harbor Frameworks provides ''adequate'' privacy protection. The Safe Harbor Lists are used by European citizens and organizations to determine whether a U.S. organization is presumed to provide ''adequate'' data protection, as well as by U.S. and European authorities to determine whether an organization has self-certified (i.e., especially when a complaint has been lodged against that organization).

Affected Public: Business or other for-profit organizations.

Frequency: Annual.

Respondent's Obligation: Voluntary.

This information collection request may be viewed at reginfo.gov. Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: November 18, 2014.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2014–27643 Filed 11–20–14; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

Bureau of the Census

[Docket Number 141016856–4856–01]

Annual Surveys in the Manufacturing Area

AGENCY: Bureau of the Census, Department of Commerce.

ACTION: Notice of Determination.

SUMMARY: The Bureau of the Census (Census Bureau) is conducting the 2015 annual surveys in the manufacturing area. The 2015 annual surveys consist of the Annual Survey of Manufactures, the Business R&D and Innovation Survey, and the Manufacturers' Unfilled Orders Survey. These annual surveys will be sent to a sample of establishments and companies that participate in manufacturing activities. We have determined that annual data collected from these surveys are needed to aid the efficient performance of essential governmental functions, and have significant application to the needs of the public and industry. The data derived from these surveys, most of which have been conducted for many years, are not publicly available from nongovernmental or other governmental sources.

ADDRESSES: The Census Bureau will furnish report forms to organizations included in the survey. Additional copies are available upon written request to the Director, U.S. Census Bureau, Washington, DC 20233–0101.

FOR FURTHER INFORMATION CONTACT: Kevin E. Deardorff, Chief, Economy-wide Statistics Division at (301) 763–6033 or via email at *kevin.e.deardorff@census.gov.*

SUPPLEMENTARY INFORMATION: The Census Bureau is authorized to conduct mandatory surveys necessary to furnish current data on the subjects covered by the major censuses authorized by Title 13, United States Code, sections 61, 81, 131, 182, 193, 224, and 225. These surveys will provide continuing and timely national statistical data on manufacturing for the period between economic censuses. The data collected in the surveys will be within the general scope and nature of those inquiries covered in the economic census. The next economic census will be conducted for the year 2017.

Annual Survey of Manufactures

The Annual Survey of Manufactures collects industry statistics, such as total value of shipments, employment, payroll, workers' hours, capital expenditures, cost of materials consumed, supplemental labor costs, and so forth. This survey is conducted on a sample basis, and covers all manufacturing industries, including data on plants under construction but not yet in operation. All data items are collected on a mandatory basis under the authority of Title 13, United States Code.

Business R&D and Innovation Survey

The Business R&D and Innovation Survey (BRDIS) measures spending on research and development activities by United States businesses. This survey replaced the Survey of Industrial Research and Development that had been collected since the 1950's. The BRDIS collects global as well as domestic spending information, more detailed information about the R&D workforce, and information regarding innovation and intellectual property from U.S. businesses. The Census Bureau collects and compiles this information in accordance with a joint project agreement between the National Science Foundation (NSF) and the Census Bureau. The NSF publishes the results in its publication series. All data items are collected on a mandatory basis under the authority of Title 13, United States Code.

Manufacturers' Unfilled Orders Survey

The Manufacturers' Unfilled Orders Survey collects data on sales and unfilled orders in order to provide annual benchmarks for unfilled orders for the monthly Manufacturers' Shipments, Inventories, and Orders (M3) survey. The monthly M3 uses the shipment and inventory data from Annual Survey of Manufactures as the source of benchmark data, however unfilled orders are not collected on the Annual Survey of Manufactures. The annual Manufacturers' Unfilled Orders will be used to determine whether it is necessary to collect unfilled orders data for specific industries on a monthly basis (on the monthly M3 survey form). All data items are collected on a mandatory basis under the authority of Title 13, United States Code.

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act (PRA) unless that collection of information displays a current valid Office of Management and Budget (OMB) control number. In accordance with the PRA, 44 U.S.C., Chapter 45, OMB approved the annual surveys under the following OMB control numbers: Annual Survey of Manufactures; 0607–0449, Business R&D and Innovation Survey; 0607–0912, Manufacturers' Unfilled Orders Survey; 0607–0561.

Based upon the foregoing, I have directed that the annual surveys in the manufacturing area be conducted for the purpose of collecting these data.

Dated: November 17, 2014.

John H. Thompson,

Director, Census Bureau.

[FR Doc. 2014–27600 Filed 11–20–14; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Proposed Information Collection; Comment Request; Services—Surveys: BE–150, Quarterly Survey of Payment Card and Bank Card Transactions Related to International Travel

AGENCY: Bureau of Economic Analysis, 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 comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before January 20, 2015.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230, or via email at *jjesup@doc.gov.*

FOR FURTHER INFORMATION CONTACT: Request for additional information or copies of the information collection instrument and instructions should be directed to Christopher Stein, Chief, Services Surveys Branch BE–50 (SSB), Bureau of Economic Analysis, U.S. Department of Commerce, Washington, DC 20230; phone: (202) 606–9850; fax: (202) 606–5318; or via email at *christopher.stein@bea.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Quarterly Survey of Payment Card and Bank Card Transactions Related to International Travel (BE–150) is a survey that collects data on the credit, debit, charge, automated teller machine (ATM), and point of sale transactions of U.S. persons traveling abroad and foreign persons traveling in the United States. The information collected on this survey will be used to formulate U.S. international economic policy and analyze the impact of that policy, and the policies of foreign countries, on international trade in services. The data are also used in estimating the travel component of the U.S. international transactions accounts (ITAs) and national income and product accounts (NIPAs).

The Bureau of Economic Analysis (BEA) is proposing no additions, modifications, or deletions to the current BE–150 survey. The effort to keep current reporting requirements unchanged is intended to minimize respondent burden while considering the needs of data users. Existing language in the instructions and definitions will be reviewed and adjusted as necessary to clarify survey requirements.

II. Method of Collection

Form BE–150 is a quarterly report that must be filed within 45 days after the end of each quarter and is mandatory for each U.S. company that operates networks for clearing and settling credit card transactions made by U.S. cardholders in foreign countries and by foreign cardholders in the United States and from PIN-based debit network companies.

BEA offers its electronic filing option, the eFile system, for use in reporting on Form BE–150. For more information about eFile, go to *www.bea.gov/efile.*

III. Data

OMB Control Number: 0608–0072.

Form Number: BE–150.

Type of Review: Regular submission.

Affected Public: Business or other for-profit organizations.

Estimated Number of Responses: 24 annually (6 filed each quarter).

Estimated Time per Response: 16 hours is the average, but may vary considerably among respondents because of differences in company size and complexity.

Estimated Total Annual Burden Hours: 384.

Estimated Total Annual Cost to Public: $0.

Respondent's Obligation: Mandatory.

Legal Authority: International Investment and Trade in Services Survey Act (Pub. L. 94–472, 22 U.S.C. 3101–3108, as amended).

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 will have practical utility; (b) the accuracy of the Agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: November 18, 2014.

Glenna Mickelson,

Management Analyst, Office of Chief Information Officer.

[FR Doc. 2014–27613 Filed 11–20–14; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–109–2014]

Approval of Subzone Status; General Electric Company; Decatur, Alabama

On August 25, 2014, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the Huntsville-Madison County Airport Authority, grantee of FTZ 83, requesting subzone status subject to the existing activation limit of FTZ 83 on behalf of General Electric Company in Decatur, Alabama.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (79 FR 51545–51546, 8/29/2014). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval.

Pursuant to the authority delegated to the FTZ Board's Executive Secretary (15 CFR Sec. 400.36(f)), the application to establish Subzone 83D is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, and further subject to FTZ 83's 2,000-acre activation limit.

Dated: November 17, 2014.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2014–27653 Filed 11–20–14; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–143–2014]

Foreign-Trade Zone 246—Waco, Texas; Application for Subzone; Spenco Medical Corporation; Waco, Texas

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the City of Waco, grantee of FTZ 246, requesting subzone status for the facility of Spenco Medical Corporation, located in Waco, Texas. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally docketed on November 17, 2014.

The proposed subzone (12.9 acres) is located at 6301 Imperial Drive in Waco. The proposed subzone would be subject to the existing activation limit of FTZ 246. No authorization for production activity has been requested at this time.

In accordance with the Board's regulations, Camille Evans of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

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 December 31, 2014. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to January 15, 2015.

A copy of the application 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 Camille Evans at *Camille.Evans@trade.gov* or (202) 482–2350.

Dated: November 17, 2014.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2014–27676 Filed 11–20–14; 8:45 am]

BILLING CODE 3510–DS–P

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: Notice of Preliminary Results of Changed Circumstances Review and Extension of the Final Results

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On June 28, 2013, the Department of Commerce (the Department) initiated a changed circumstances review (CCR) of the antidumping duty (AD) order on tapered roller bearings (TRBs) and parts thereof, finished and unfinished, from the People's Republic of China (PRC) in order to determine whether Shanghai General Bearing Co., Ltd. (SGBC/SKF), a producer/exporter of TRBs in the PRC, is the successor-in-interest to a company revoked from the AD order on TRBs in 1997 (also known as ''SGBC''). We preliminarily determine that SGBC/SKF is the successor-in-interest to SGBC. Interested parties are invited to comment on these preliminary results.

DATES: *Effective Date:* November 21, 2014.

FOR FURTHER INFORMATION CONTACT: Stephen Banea, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0656.

SUPPLEMENTARY INFORMATION:

Background

On June 15, 1987, the Department published in the **Federal Register** the AD order on TRBs from the PRC.[1] On February 11, 1997, the Department revoked the order on TRBs from the PRC with respect to merchandise produced and exported by SGBC, effective as of June 1, 1994.[2]

Effective August 1, 2012, the majority shareholder of SGBC, the General Bearing Corporation (GBC), merged with AB SKF (SKF) and, as a result of the merger, both GBC and SGBC became part of the SKF Group. On February 13, 2013, SGBC/SKF [3] requested that the Department conduct a CCR pursuant to 19 CFR 351.221(c)(3)(ii) to determine whether it is the successor-in-interest to SGBC as it existed prior to its affiliation with SKF.

On June 28, 2013, the Department published in the **Federal Register** a notice initiating a CCR to address this question.[4] Between July 2013 and February 2014, the Department requested additional information from SGBC/SKF, and SGBC/SKF submitted its responses to these requests from August 2013 through March 2014. Between September 2013 and July 2014, we received comments on SGBC/SKF's submissions from the Timken Company, the petitioner in this proceeding. In December 2013, we also received comments from Stemco LP (Stemco), a U.S. manufacturer and importer of TRBs.

Scope of the Order

Imports covered by the order are shipments of tapered roller bearings and parts thereof, finished and unfinished, from the People's Republic of China; flange, take up cartridge, and hanger units incorporating tapered roller bearings; and tapered roller housings (except pillow blocks) incorporating tapered rollers, with or without spindles, whether or not for automotive use. These products are currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) item numbers 8482.20.00, 8482.91.0050, 8482.99.15, 8482.99.45, 8483.20.40, 8483.20.80, 8483.30.80, 8483.90.20, 8483.90.30, 8483.90.80, 8708.70.6060, 8708.99.2300, 8708.99.4850, 8708.99.6890, 8708.99.8115 and, 8708.99.8180. Although the HTSUS item numbers are provided for convenience and customs purposes, the

[1] *See Antidumping Duty Order: Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People's Republic of China,* 52 FR 22667 (June 15, 1987).

[2] *See Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Revocation in Part of Antidumping Duty Order,* 62 FR 6189, 6214 (February 11, 1997).

[3] Hereinafter, we refer to the post-merger company as SGBC/SKF and the pre-merger entity as SGBC.

[4] *See Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the People's Republic of China: Initiation of Antidumping Duty Changed Circumstances Review,* 78 FR 38943 (June 28, 2013).

written description of the scope of the order is dispositive.

Successor-in-Interest Determination

In accordance with section 751(b)(1) of the Tariff Act of 1930, as amended (the Act), we are conducting this CCR based upon the information contained in SGBC/SKF's and other interested parties' submissions. In making a successor-in-interest determination, the Department examines several factors, including, but not limited to, changes in the following: (1) Management; (2) production facilities; (3) supplier relationships; and (4) customer base.[5] While no single factor or combination of factors will necessarily provide a dispositive indication of a successor-in-interest relationship, generally, the Department will consider the new company to be the successor to the previous company if the new company's resulting operation is not materially dissimilar to that of its predecessor.[6] Thus, if the record evidence demonstrates that, with respect to the production and sale of the subject merchandise, the new company operates as the same business entity as the predecessor company, the Department will generally accord the new company the same AD treatment as its predecessor.[7]

SGBC was revoked from the order in 1997 and became part of the SKF Group in 2012. In conducting a successor-in-interest analysis, while we generally consider information from immediately before and after the formation of a new entity, the Department considers all information on the record relevant to the determination.[8] In the instant case, we compared SGBC/SKF to the entity that was revoked from the order, and we considered the changes to that entity since revocation.

Preliminary Results

We preliminarily find SGBC/SKF to be the successor-in-interest to SGBC because the information on the record indicates that SGBC/SKF continues to operate as essentially the same entity that was revoked from the order. Although there were changes in SGBC's production process and board membership after revocation, these changes were made over a number of years and do not appear to be linked to changes in ownership structure. Rather, they are changes generally in the normal course of business that would occur over such a long period (*i.e.,* approximately two decades). Thus, after considering the facts on the record as a whole, we do not find that SGBC/SKF's operations (based on an examination of its management, production facilities, supplier relationships, and customer base), changed so significantly such that we would find that that it is a different entity from SGBC. For the Department's detailed analysis, see the Preliminary Decision Memorandum.[9]

Public Comment

Pursuant to 19 CFR 351.310(c), any interested party may request a hearing within 10 business days of publication of this notice.[10] Parties will be notified of the time and date of any hearing, if requested. Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs and/or written comments not later than 10 business days after the publication of this notice. Rebuttal briefs, and rebuttals to written comments, which must be limited to issues raised in such briefs or comments, may be filed not later than 15 business days after the date of publication of this notice.[11] Parties who submit case briefs or rebuttal briefs in this CCR are requested to submit with each argument: (1) A statement of the issue; and (2) a brief summary of the argument; and (3) a table of authorities.

Interested parties who wish to comment on the preliminary results must file briefs electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (IA ACCESS). IA ACCESS is available to registered users at *http://iaaccess.trade.gov.* An electronically-filed document must be received successfully in its entirety by the Department's electronic records system, IA ACCESS, by 5 p.m. Eastern Time on the date the document is due.

Final Results of the Review

In accordance with 19 CFR 351.216(e), the final results of this CCR are due on November 29, 2014. However, 19 CFR 351.302(b) provides that the Department may, for good cause, extend any time limit unless expressly precluded by statute. Therefore, to provide time for an adequate briefing schedule and to analyze the comments received, if any, we are extending the time period for issuing the final results of this CCR until January 31, 2015.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(b) and 777(i)(1) of the Act, and 19 CFR 351.216 and 351.221.

Dated: November 17, 2014.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2014–27683 Filed 11–20–14; 8:45 am]

BILLING CODE 3510–DS–P

[5] *See, e.g., Pressure Sensitive Plastic Tape from Italy: Preliminary of Antidumping Duty Changed Circumstances Review,* 75 FR 8925 (February 26, 2010), unchanged in *Pressure Sensitive Plastic Tape from Italy: Final Results of Antidumping Duty Changed Circumstances Review,* 75 FR 27706 (May 18, 2010); and *Brake Rotors from the People's Republic of China: Final Results of Changed Circumstances Antidumping Duty Administrative Review,* 70 FR 69941 (November 18, 2005) (*Brake Rotors*), citing *Brass Sheet and Strip from Canada: Final Results of Antidumping Duty Administrative Review,* 57 FR 20460 (May 13, 1992).

[6] *See, e.g., Brake Rotors.*

[7] *Id.; see also, e.g., Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review: Certain Frozen Warmwater Shrimp from India,* 77 FR 64953 (October 24, 2012), unchanged in *Final Results of Antidumping Duty Changed Circumstances Review: Certain Frozen Warmwater Shrimp from India,* 77 FR 73619 (December 11, 2012).

[8] *See Certain Pasta from Italy: Notice of Preliminary Results of Antidumping Duty Changed Circumstances Review,* 79 FR 28481, 28482 (May 16, 2014), unchanged in *Certain Pasta from Italy: Notice of Final Results of Antidumping Duty Changed Circumstances Review,* 79 FR 56339 (September 19, 2014).

[9] *See* the memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance entitled, ''Decision Memorandum for Preliminary Results of Antidumping Duty Changed Circumstances Review Requested by Shanghai General Bearing Company: Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the People's Republic of China,'' dated concurrently with these results and hereby adopted by this notice (Preliminary Decision Memorandum).

[10] This regulation authorizes the Department to alter the time limit for requesting a hearing; *see also* 19 CFR 351.303 for general filing requirements.

[11] This regulation authorizes the Department to alter the time limit for submitting case briefs.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–849]

Certain Cut-to-Length Carbon Steel Plate From the People's Republic of China: Preliminary Results of Antidumping Administrative Review; 2012–2013

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* November 21, 2014.

SUMMARY: The Department of Commerce (''Department'') is conducting an administrative review of the antidumping duty order on certain cut-to-length carbon steel plate (''CTL plate'') from the People's Republic of China (''PRC'') for the period of review (''POR'') November 1, 2012, through October 31, 2013. This review covers

two PRC companies.[1] The Department preliminarily finds that one of the two companies, Hunan Valin, did not have reviewable transactions during the POR. Further, the Department finds that the other company, Zhengzhou Shangdao, is part of the PRC-wide entity to which the Department has assigned a dumping margin based on total adverse facts available (''AFA'').

FOR FURTHER INFORMATION CONTACT: Patrick O'Connor, AD/CVD Operations, Office IV, Enforcement & Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0989.

SUPPLEMENTARY INFORMATION:

Scope of the Order

The product covered by the order is certain cut-to-length carbon steel plate from the PRC.[2] This merchandise is currently classified in the Harmonized Tariff Schedule of the United States (''HTSUS'') under item numbers 7208.40.3030, 7208.40.3060, 7208.51.0030, 7208.51.0045, 7208.51.0060, 7208.52.0000, 7208.53.0000, 7208.90.0000, 7210.70.3000, 7212.40.5000, and 7212.50.0000. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.

Methodology

The Department has conducted this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (''the Act''). For a full description of the methodology underlying our conclusions, *see* Preliminary Results Decision Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, dated concurrently with these results and hereby adopted by this notice. This memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''). IA ACCESS is available to registered users at *http://iaaccess.trade.gov* and in the Central Records Unit, room 7046 of the main Department of Commerce building. In addition, a complete version of the Preliminary Results Decision Memorandum can be accessed directly on the Internet at *http://www.trade.gov/enforcement/.* The signed Preliminary Results Decision Memorandum and the electronic versions of the Preliminary Results Decision Memorandum are identical in content.

Preliminary Results of Review

The Department preliminarily determines that the following weighted-average dumping margin exists for the POR:

Exporter	Weighted-Average dumping margin (percent)
PRC-Wide Entity[3]	128.59

In addition, the Department preliminarily determines that Hunan Valin did not have reviewable transactions during the POR.

Disclosure and Public Comment

Interested parties are invited to comment on the preliminary results and may submit case briefs and/or written comments, filed electronically using IA ACCESS, within 30 days of the date of publication of this notice, pursuant to 19 CFR 351.309(c)(1)(ii). Rebuttal briefs, limited to issues raised in the case briefs, will be due five days after the due date for case briefs, pursuant to 19 CFR 351.309(d). Parties who submit case or rebuttal briefs in this proceeding are requested to submit with each argument a statement of the issue, a summary of the argument not to exceed five pages, and a table of statutes, regulations, and cases cited, in accordance with 19 CFR 351.309(c)(2).

Pursuant to 19 CFR 351.310(c), interested parties, who wish to request a hearing, or to participate in a hearing if one is requested, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, filed electronically using IA ACCESS. Electronically filed case briefs/written comments and hearing requests must be received successfully in their entirety by the Department's electronic records system, IA ACCESS, by 5:00 p.m. Eastern Standard Time, within 30 days after the date of publication of this notice.[4] Hearing requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those issues raised in the respective case briefs. If a request for a hearing is made, parties will be notified of the time and date of the hearing which will be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington DC 20230. The Department intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuance of the final results, the Department will determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries covered by this review.[5] The Department intends to issue assessment instructions to CBP 15 days after the publication date of the final results of this review. The Department intends to instruct CBP to liquidate entries of subject merchandise from the PRC-wide entity, including entries of subject merchandise from Zhengzhou Shangdao, at 128.59 percent (the PRC-wide rate). Additionally, pursuant to the Department's practice in NME cases, if we continue to determine that Hunan Valin had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the PRC-wide rate. For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of review, as provided by section 751(a)(2)(C) of the Act: (1) For Hunan Valin, which had no shipments, the cash deposit rate will

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part,* 78 FR 79392 (December 30, 2013). The companies under review are as follows: Hunan Valin Xiangtan Iron & Steel Co. Ltd. (''Hunan Valin''), and Zhengzhou Shangdao Iron & Steel Co. (''Zhengzhou Shangdao'').

[2] *See* Decision Memorandum for Preliminary Results of Antidumping Duty Administrative Review: Certain Cut-to-Length Carbon Steel Plate from the People's Republic of China, issued concurrently with this notice, for a complete description of the Scope of the Order (''Preliminary Results Decision Memorandum'').

[3] Including Zhengzhou Shangdao.

[4] *See* 19 CFR 351.310(c).

[5] *See* 19 CFR 351.212(b)(1).

remain unchanged from the rate assigned to this company in the most recently completed review of the company; (2) for previously investigated or reviewed PRC and non-PRC exporters which are not under review in this segment of the proceeding but which have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate, including Zhengzhou Shangdao, the cash deposit rate will be the PRC-wide rate of 128.59 percent; and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter(s) that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213.

Dated: November 7, 2014.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Results Decision Memorandum

Summary
Background
Scope of the Order
Discussion of the Methodoogy
Preliminary Determination of No Shipments
Separate Rates
Application of Adverse Facts Available
Corroboration of Secondary Information Used as AFA
Duty Evasion
Recommendation

[FR Doc. 2014–27292 Filed 11–20–14; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[Application No. 14–00002]

Export Trade Certificate of Review

ACTION: Notice of Application for an Export Trade Certificate of Review for JDE USA LLC Application no. 14–00002.

SUMMARY: The Office of Trade and Economic Analysis (''OTEA'') of the International Trade Administration, Department of Commerce, has received an application for an Export Trade Certificate of Review (''Certificate''). This notice summarizes the application and requests comments relevant to whether the Certificate should be issued.

FOR FURTHER INFORMATION CONTACT: Joseph Flynn, Director, Office of Trade and Economic Analysis, International Trade Administration, (202) 482–5131 (this is not a toll-free number) or email at *etca@trade.gov.*

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from State and Federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. Section 302(b)(1) of the Export Trading Company Act of 1982 and 15 CFR 325.6(a) require the Secretary to publish a notice in the **Federal Register** identifying the applicant and summarizing its proposed export conduct.

Request for Public Comments

Interested parties may submit written comments relevant to the determination whether a Certificate should be issued. If the comments include any privileged or confidential business information, it must be clearly marked and a nonconfidential version of the comments (identified as such) should be included. Any comments not marked as privileged or confidential business information will be deemed to be nonconfidential.

An original and five (5) copies, plus two (2) copies of the nonconfidential version, should be submitted no later than 20 days after the date of this notice to: Export Trading Company Affairs, International Trade Administration, U.S. Department of Commerce, Room 7025–X, Washington, DC 20230.

Information submitted by any person is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). However, nonconfidential versions of the comments will be made available to the applicant if necessary for determining whether or not to issue the Certificate. Comments should refer to this application as ''Export Trade Certificate of Review, application number 14–00002.''

A summary of the current application follows.

Summary of the Application

Applicant: JDE USA LLC, 1180 Oakshore Lane, Antioch IL 60002.

Contact: Manager, Moise Wetu.

Application No.: 14–00002.

Date Deemed Submitted: October 30, 2014

Summary: JDE USA LLC (''JDE'') seeks a Certificate of Review to engage in the Export Trade Activities and Methods of Operation described below in the following Export Trade and Export Markets:

Export Trade

Products: All Products.

Services: All services related to the export of Products.

Technology Rights: All intellectual property rights associated with Products or Services, including, but not limited to: Patents, trademarks, services marks, trade names, copyrights, neighboring (related) rights, trade secrets, know-how, and confidential databases and computer programs.

Export Trade Facilitation Services (as They Relate to the Export of Products): Export Trade Facilitation Services, including but not limited to: Consulting and trade strategy, arranging and coordinating delivery of Products to the port of export; arranging for inland and/or ocean transportation; allocating Products to vessel; arranging for storage space at port; arranging for warehousing, stevedoring, wharfage, handling, inspection, fumigation, and freight forwarding; insurance and financing; documentation and services related to compliance with customs' requirements; sales and marketing; export brokerage; foreign marketing and analysis; foreign market development; overseas advertising and promotion; Products-related research and design based upon foreign buyer and consumer preferences; inspection and quality control; shipping and export management; export licensing; provisions of overseas sales and distribution facilities and overseas sales staff; legal; accounting and tax

assistance; development and application of management information systems; trade show exhibitions; professional services in the area of government relations and assistance with federal and state export assistance programs (e.g., Export Enhancement and Market Promotion programs, invoicing (billing) foreign buyers; collecting (letters of credit and other financial instruments) payment for Products; and arranging for payment of applicable commissions and fees).

Export Markets

The Export Markets include all parts of the world except the United States (the fifty states of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands).

Export Trade Activities and Methods of Operations

To engage in Export Trade in the Export Markets, JDE may:

1. Provide and/or arrange for the provision of Export Trade Facilitation Services;

2. Engage in promotional and marketing activities and collect information on trade opportunities in the Export Markets and distribute such information to clients;

3. Enter into exclusive and/or non-exclusive licensing and/or sales agreements with Suppliers for the export of Products and Services, and/or Technology Rights to Export Markets;

4. Enter into exclusive and/or non-exclusive agreements with distributors and/or sales representatives in Export Markets;

5. Allocate export sales or divide Export Markets among Suppliers for the sale and/or licensing of Products and Services and/or Technology Rights;

6. Allocate export orders among Suppliers;

7. Establish the price of Products and Services and/or Technology Rights for sales and/or licensing in Export Markets; and

8. Negotiate, enter into, and/or manage licensing agreements for the export of Technology Rights.

9. JDE may exchange information with individual Suppliers on a one-to-one basis regarding that Supplier's inventories and near-term production schedules in order that the availability of Products for export can be determined and effectively coordinated by JDE with its distributors in Export Markets.

Definition

''Supplier'' means a person who produces, provides, or sells Products, Services, and/or Technology Rights.

Dated: November 7, 2014.

Joseph Flynn,

Director, Office of Trade and Economic Analysis, International Trade Administration. (202) 482–5131 etca@trade.gov.

[FR Doc. 2014–26932 Filed 11–20–14; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD596

Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Issuance of a Scientific Purposes and Enhancement of Survival Permit for a Hatchery and Genetic Management Plan (HGMP).

SUMMARY: This notice announces the availability of the Final Environmental Assessment (EA) on the application from the California Department of Fish and Wildlife (CDFW), Region 1 for a Scientific Purposes and Enhancement of Survival Permit for a Hatchery and Genetic Management Plan (HGMP) for take of a threatened species in accordance with the Endangered Species Act (ESA). This notice also announces that NMFS has made a decision to issue a permit (Permit No. 15755) to CDFW for activities described in their HGMP, and has authorized the Hatchery and Genetic Management Plan (HGMP) for the Iron Gate Hatchery coho salmon program in the Klamath River watershed in California.

This notice is provided under National Environmental Policy Act (NEPA) regulations and NMFS ESA permit regulations to inform the public that the Final EA, HGMP, responses to public comments, and associated documents are available for review.

ADDRESSES: The application, permit, final HGMP, Final EA, and related documents are available for review by appointment at: California Coastal Area Office, NMFS, 1655 Heindon Road, Arcata, CA 95521 (ph: 707–825–5171, fax: 707–825–4840, email at: *jim.simondet@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Jim Simondet at 707–825–5171, or email: *jim.simondet@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Authority

The issuance of Scientific Purposes and Enhancement of Survival Permit permits by NMFS, as required by the Endangered Species Act of 1973 (16 U.S.C. 1531–1543) (ESA), is based on a finding that such permits: (1) Are applied for in good faith; (2) would not operate to the disadvantage of the listed species which are the subject of the permits; and (3) are consistent with the purposes and policies set forth in section 2 of the ESA. Authority to take listed species is subject to conditions set forth in the permits. Permits and modifications are issued in accordance with and are subject to the ESA and NMFS regulations (50 CFR parts 222–226) governing listed fish and wildlife permits.

Species Covered in This Notice

This notice is relevant to federally threatened Southern Oregon/Northern California Coast coho salmon (*Oncorhynchus kisutch*).

Background

On January 8, 2013 NMFS announced in the **Federal Register** a notice of receipt of a Scientific Purposes and Enhancement of Survival Permit application and draft Hatchery and Genetic Management Plan (HGMP) from the California Department of Fish and Game, now Wildlife (CDFW), for a 10 year period (78 FR 1201). On January 30, 2013 NMFS published a corrected **Federal Register** notice with clarifications regarding the comment period (78 FR 6298) which ended March 1, 2013. The draft HGMP specified methods of operation for the Iron Gate hatchery coho salmon program located along the Klamath River, within the State of California. NMFS also announced the availability of a Draft Environmental Assessment (EA) regarding issuance of a permit authorizing take of coho salmon associated with implementation of the HGMP. Public review and comment were invited on both the draft HGMP and the draft EA. The public review and comment period ended on March 1, 2013. NMFS did not receive any comment letters on the Draft HGMP or the Draft EA during the public review period.

The HGMP will be implemented as part of the existing coho salmon artificial propagation program at Iron Gate Hatchery. Actions taken pursuant to the permit are designed to enhance the survival of coho salmon residing in the Upper Klamath River below Iron Gate Dam. The HGMP incorporates two

main components: Artificial propagation and monitoring and evaluation (M&E). Artificial propagation activities that could lead to the take of listed coho salmon include: Adult broodstock collection, spawning, rearing, handling, evaluation, tagging and release of progeny. Once the threat of demographic extinction is reduced, the number of hatchery adult coho salmon allowed to spawn naturally in Bogus Creek may be controlled to insure that the proportionate natural influence (PNI) for spawning coho salmon exceeds 0.5 (PNI > 0.5). The purpose for controlling the PNI is to have natural environment rather than the hatchery environment drive local adaptation and selection processes to improve genetic fitness. The HGMP includes measures to increase the fertilization of eggs and survival rate for each life stage and to minimize the likelihood of genetic or ecological effects to listed natural fish resulting from the hatchery operations and propagation of hatchery fish. Monitoring and evaluation will occur by conducting coho spawning ground and carcass surveys in the mainstem Klamath River and key tributary streams that comprise habitat for the Upper Klamath River coho salmon population unit. These data will be used to estimate adult natural and hatchery escapement levels and spawn timing in key streams for the Upper Klamath population unit as a whole. M&E activities will also collect necessary data to document achievement of performance indicators specified in the HGMP.

Take of adult and juvenile coho salmon associated with Permit 15755 is described in the NMFS permit and particularly detailed in Table 1 of the permit. Permit 15755 expires on August 31, 2024.

Dated: November 17, 2014.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2014–27543 Filed 11–20–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD526

Fisheries of the South Atlantic; Southeast Data, Assessment and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 40 Review Workshop for Atlantic menhaden (*Brevoortia tyrannus*).

SUMMARY: The SEDAR 40 review of the Atlantic stock of menhaden will consist of one workshop.

DATES: The SEDAR 40 Review Workshop will be held on December 9, 2014, from 9 a.m. until 6 p.m.; December 10, 2014, from 8 a.m. until 6 p.m.; and December 11, 2014, from 8 a.m. until 1 p.m. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from, or completed prior to the time established by this notice.

ADDRESSES:

Meeting address: The SEDAR 40 Review Workshop will be held at the Doubletree by Hilton Atlantic Beach Oceanfront Hotel, 2717 West Fort Macon Road, Atlantic Beach, NC 28512; telephone: (252) 240–1155.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julia Byrd, SEDAR Coordinator; telephone: (843) 571–4366; email: *julia.byrd@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, the Atlantic and Gulf States Marine Fisheries Commissions and NOAA Fisheries Southeast Regional Office and Southeast Fisheries Science Center. Participants include: Data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The Review Workshop is an independent peer review of the assessment developed during the assessment process, which may include Data and Assessment Workshops. Workshop Panelists will review the assessment and document their comments and recommendations in a Review Panel Summary.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the SEDAR office (see **ADDRESSES**) at least 10 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: November 18, 2014.

Tracey L. Thompson,

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

[FR Doc. 2014–27620 Filed 11–20–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD634

North Pacific Fishery Management Council; Public Meetings

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meetings.

SUMMARY: The North Pacific Fishery Management Council (Council) and its advisory committees will hold public meetings, December 10–16, 2014.

DATES: The Council will begin its plenary session at 8 a.m. on Wednesday December 10, continuing through Tuesday December 16, 2014. The Scientific Statistical Committee (SSC) will begin at 8 a.m. on Monday December 8 and continue through Wednesday December 10, 2014. The Council's Advisory Panel (AP) will begin at 8 a.m. on Tuesday December 9, and continue through Saturday December 13, 2014. The Enforcement Committee will meet from 1 p.m. to 4 p.m. on Tuesday December 9, 2014. All meetings are open to the public, except executive sessions.

ADDRESSES: The meetings will be held at the Anchorage Hilton Hotel, 500 West 3rd, Anchorage, AK.

Council Address: North Pacific Fishery Management Council, 605 W. 4th Avenue, Suite 306, Anchorage, AK 99501–2252.

FOR FURTHER INFORMATION CONTACT: David Witherell, Council staff; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION:

Council Plenary Session: The agenda for the Council's plenary session will include the following issues. The Council may take appropriate action on any of the issues identified.

1. Executive Director's Report (including review of staff work plan for Gulf of Alaska (GOA)) trawl bycatch management, crab workgroup report on regional delivery framework agreement, legislate update)
   - NMFS Management Report
   - ADF&G Report
   - NOAA Enforcement Report
   - U.S. Coast Guard Report
   - U.S. FWS Report
   - International Pacific Halibut Commission Report
   - Protected Species Report
   - North Pacific Research Board report
2. Charter Halibut Management Measures for 2015
3. Initial review of Bering Sea Salmon Bycatch
4. Final action on GOA Skate Maximum Retainable Allowance (MRA)
5. Final BSAI Groundfish harvest specifications; approve Plan Team reports; Amendment 80/American Fisheries Act (AFA) incidental catch data
6. Final GOA groundfish specifications; approve Plan Team reports
7. Initial review of GOA Sablefish longline pots
8. Discussion paper on Vessel Individual Fishing Quotas (IFQs) Caps
9. Electronic Monitoring (EM); workgroup report; discuss Alternative 4 and review Cooperative Research Plan (CRP)
10. Discussion paper on Observer coverage on small Catcher Processors (CPs)
11. Review Vessel Monitoring System (VMS) discussion paper
12. Initial/Final action on Fishery Management Plan (FMP) language License Limitation Program (LLP) exemptions housekeeping
13. Pribilof canyon corals; receive comments on rage of alternatives
14. Staff Tasking

The Advisory Panel will address most of the same agenda issues as the Council except B reports. The SSC agenda will include the following issues:

1. Bering Sea Salmon Bycatch
2. BSAI Groundfish Specifications
3. GOA Groundfish Specifications
4. GOA Sablefish pots

In addition to providing ongoing scientific advice for fishery management decisions, the SSC functions as the Councils primary peer review panel for scientific information as described by the Magnuson-Stevens Act section 302(g)(1)(e), and the National Standard 2 guidelines (78 FR 43066). The peer review process is also deemed to satisfy the requirements of the Information Quality Act, including the OMB Peer Review Bulletin guidelines.

The Agenda is subject to change, and the latest version will be posted at *http://www.npfmc.org.* Background documents, reports, and analyses for review are posted on the Council Web site in advance of the meeting. The names and organizational affiliations of SSC members are also posted on the Web site.

Although non-emergency issues not contained in this agenda may come before these groups for discussion, those issues may not be the subject of formal action during these meetings. 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 the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Gail Bendixen at (907) 271–2809 at least 7 working days prior to the meeting date.

Dated: November 17, 2014.

Tracey L. Thompson,

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

[FR Doc. 2014–27540 Filed 11–20–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD635

Mid-Atlantic Fishery Management Council (MAFMC); Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will hold public meetings of the Council and its Committees.

DATES: The meetings will be held Monday, December 8, 2014 through Thursday, December 11, 2014. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held at: Royal Sonesta, 550 Light Street, Baltimore, MD, telephone: (410) 234–0550.

Council Address: Mid-Atlantic Fishery Management Council, 800 N. State St., Suite 201, Dover, DE 19901; telephone: (302) 674–2331.

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council; telephone: (302) 526–5255. The Council's Web site, *www.mafmc.org* also has details on the meeting location, proposed agenda, webinar listen-in access, and briefing materials.

SUPPLEMENTARY INFORMATION: The following items are on the agenda, though agenda items may be addressed out of order (changes will be noted on the Council's Web site when possible.)

Monday, December 8, 2014

1:30 p.m.–5 p.m.

Executive Committee [OPEN SESSION]—Ecosystem Approach to Fisheries Management

- Forage Fish White Paper (review second draft)

1. Consider potential action for protection of unmanaged forage species
- Climate Change and Fisheries White Paper (review first draft)
—2015 Implementation Plan
- Discuss and approve

Tuesday, December 9, 2014

9 a.m.–12:30 p.m.

Ecosystem/Ocean Planning Committee Meeting as a Committee of the Whole
—Habitat Project Update
—NEFMC Omnibus Habitat Amendment Public Hearing
—Develop Council comments on NEFMC Amendment

1:30 p.m.

Demersal Committee Meeting as a Committee of the Whole with the Atlantic States Marine Fisheries Commission's Summer Flounder, Scup, and Black Sea Bass Boards

1:30 p.m.–5 p.m.

Comprehensive Summer Flounder Amendment
—Review Summer Flounder Scoping comments
—Approve issues to be addressed in the amendment

Wednesday, December 10, 2014

9 a.m.

Demersal Committee Meeting as a Committee of the Whole with the Atlantic States Marine Fisheries Commission's Summer Flounder, Scup, and Black Sea Bass Boards

9 a.m.–10:30 a.m.

Finalize Summer Flounder 2015 Recreational Management Measures
—Review Monitoring Committee and Advisory Panel recommendations for 2015
—Adopt recommendations for 2015 management measures

10:30 a.m.–12 p.m.

Finalize Scup 2015 Recreational Management Measures
—Review Monitoring Committee and Advisory Panel recommendations for 2015
—Adopt recommendations for 2015 management measures

1 p.m.–3 p.m.

Finalize Black Sea Bass 2015 Management Measures
—Review Monitoring Committee and Advisory Panel recommendations for 2015
—Adopt recommendations for 2015 management measures

3 p.m.–4 p.m.

Greater Atlantic Regional Fisheries Office Strategic Plan, *Harry Mears*

4 p.m.–5 p.m.

Golden Tilefish
—Consider changes in possession limit
—Consider changes to the Interactive Voice Reporting requirements

5 p.m.–6 p.m.

Listening Session—Deep Sea Corals, *Martha Nizinski*

Thursday, December 11, 2014

9 a.m.

Council Convenes

9 a.m.–1 p.m.

Business Session
Organization Reports
—NMFS Greater Atlantic Regional Office
—NMFS Northeast Fisheries Science Center
—NOAA Office of General Counsel
—NOAA Office of Law Enforcement
—U.S. Coast Guard
—Atlantic States Marine Fisheries Commission
Liaison Reports
—New England Council
—South Atlantic Council
Executive Director's Report, *Chris Moore*
Science Report, *Rich Seagraves*
Committee Reports
—Executive Committee
- Approve 2015 Implementation Plan Continuing and New Business

Although non-emergency issues not contained in this agenda may come before this group for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), those issues may not be the subject of formal action during these meetings. Actions will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under Section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to the meeting date.

Dated: November 17, 2014.

Tracey L. Thompson,

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

[FR Doc. 2014–27541 Filed 11–20–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD622

Caribbean Fishery Management Council; Public Meeting

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 (Council) will hold its 151st meeting.

DATES: The meeting will be held on December 9–10, 2014. The Council will convene on Tuesday, December 9, 2014, from 9 a.m. to 6 p.m., and will reconvene on Wednesday, December 10, 2014, from 9 a.m. to 5 p.m.

ADDRESSES: The meeting will be held at the Marriott Resort Frenchman's Reef & Morning Star, #4 Estate Bakkeroe, St. Thomas, U.S.V.I. 00802.

FOR FURTHER INFORMATION CONTACT: Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico 00918; telephone: (787) 766–5926.

SUPPLEMENTARY INFORMATION: The Council will hold its 151st regular Council Meeting to discuss the items contained in the following agenda:

December 9, 2014, 9 a.m.–6 p.m.

- Call to Order
- Adoption of Agenda
- Consideration of 150th Council Meeting Verbatim Transcriptions
- Executive Director's Report
- Abril/Bajo/Tourmaline Reconsideration of Closure Period, Guidance on Next Steps from Council
- SSC Outcomes from November one-day Webinar Meeting, Including Status of Species Selection Criteria Table
- ACL Overages/AM Application/ Enhanced Reporting Status
- Timing of Closures, Focus on Development of Options Paper and Scheduling Additional Scoping Hearings
- Federal Permits Scoping Document, Schedule Scoping Meetings

- Red Hind White Paper

Public Comment Period

(5-minutes presentations)

5:15 p.m.–6 p.m.

- Administrative Matters
  - —Budget Update FY 2014/15
  - —SOPPs Approval for Submission to NOAA Fisheries
  - —SSC/OEAP Memberships
  - —Closed Session to Discuss Membership of Island-Based District Advisory Panels (DAPs) and Consideration of Terms of Reference for Winter 2015 DAP Meetings

December 10, 2014, 9 a.m.–5 p.m.

- Point 97 Presentation on Electronic Reporting Project
- Outreach and Education Report—Dr. Alida Ortíz
- Petition Shark Quota for Artisanal US Caribbean Fishers—Marcos Hanke
- SEDAR Developments and Planning—Bonnie Ponwith
- Sea Cucumbers and Sea Urchins Report from PR DNER and Consideration of need to Close Harvest in Federal Waters in Support of Implementing Harvest Closure in State Waters.
- Enforcement Issues:
  - —Puerto Rico-DNER
  - —U.S. Virgin Islands-DPNR
  - —U.S. Coast Guard
  - —NMFS/NOAA
- Meetings Attended by Council Members and Staff

Public Comment Period

(5-minute presentations)

- Other Business
- Next Council Meeting

The established times for addressing items on the agenda may be adjusted as necessary to accommodate the timely completion of discussion relevant to the agenda items. To further accommodate discussion and completion of all items on the agenda, the meeting may be extended from, or completed prior to the date established in this notice.

The meeting is open to the public, and will be conducted in English. Fishers and other interested persons are invited to attend and participate with oral or written statements regarding agenda issues.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be subjects for formal action during this meeting. Actions will be restricted to those issues specifically identified in this notice, and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided that the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

The meeting is 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, telephone (787) 766–5926, at least 5 days prior to the meeting date.

Dated: November 18, 2014.

Tracey L. Thompson,

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

[FR Doc. 2014–27621 Filed 11–20–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD633

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The North Pacific Fishery Management Council (Council) Charter Management Implementation Committee will meet in Anchorage, AK.

DATES: The meeting will be held on December 8, 2014, from 3 p.m. to 5 p.m. (AST).

ADDRESSES: The meeting will be held at the North Pacific Fishery Management Council, 605 W. 4th Avenue, Conference Room 205, Anchorage, AK. The meeting will be accessible via teleconference: (907) 271–2896.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252.

FOR FURTHER INFORMATION CONTACT: Steve MacLean, Council staff; telephone: (907) 271–2809.

SUPPLEMENTARY INFORMATION: The committee will meet to review analyses of potential Area 2C and Area 3A charter halibut management measures for 2015, and to make a recommendation for the Council to consider at its December, 2014 meeting. Potential management measures were posted on the Council Web site at *http://www.npfmc.org/halibut-charter-management/charter-management-implementation-committee/.*

Although non-emergency issues not contained in this agenda may come before these groups for discussion, those issues may not be the subject of formal action during this meeting. 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 the public has been notified of the Council's intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Gail Bendixen at (907) 271–2809 at least 7 working days prior to the meeting date.

Dated: November 18, 2014.

Tracey L. Thompson,

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

[FR Doc. 2014–27622 Filed 11–20–14; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XD607

Marine Mammals; File No. 18824

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Briana Witteveen, Ph.D., of the University of Alaska, Fairbanks, Kodiak Seafood and Marine Science Center (118 Trident Way, Kodiak, AK, 99615), has applied in due form for a permit to take multiple cetacean species for purposes of scientific research, with additional takes of several pinniped species by incidental harassment, within the Gulf of Alaska.

DATES: Written, telefaxed, or email comments must be received on or before December 22, 2014.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the *Features* box on the Applications and Permits for Protected

Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 18824 from the list of available applications.

These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov.* Please include the File No. (18824) in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Courtney Smith or Jennifer Skidmore, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), and the Fur Seal Act of 1966, as amended (16 U.S.C. 1151 *et seq.*).

The above listed applicant requests a five-year permit to conduct scientific research on cetaceans year-round within the Gulf of Alaska. The purpose of this research is to improve understanding of the foraging behavior, prey use, and habitat overlap among sympatric whale species throughout their habitat. All research will involve non-lethal take using vessels to collect identification photographs, recording of vocalizations, biopsy sampling, prey parts, sloughed skin, suction cup attachment of tags and documenting behavioral response to acoustic deterrents. The species and annual takes requested for these research activities include: Humpback whales (*Megaptera novaeangliae;* 1000); Fin whales (*Balaenoptera physalus;* 1000); Killer whales (*Orcinus orca;* 1000); Gray whales (*Eschrichtius robustus;* 1000); Sei whales (*Balaenoptera borealis;* 70); North Pacific Right whales (*Eubaelana glacialis;* 50); Sperm whales (*Physeter macrocephalus;* 70); Minke whales (*Balaenoptera acutorostrata;* 70); and Blue whales (*Balaenoptera musculus;* 50). Additionally, up to 100 of each of the following species: Harbor Porpoise (*Phocoena phocoena*), Dall's porpoise (*Phocoena dalli*), and Pacific white-sided dolphins (*Lagenorhynchus obliquidens*), and up to 50 of Northern Fur seals (*Callorhinus ursinus),* Harbor seals (*Phoca vitulina*), Steller sea lion (*Eumetopias jubatus*) are requested to be taken annually, per species, by incidental harassment. Finally, the applicant requests to transport up to 50 biological samples from each species group (pinniped and cetacean) for archived storage or analysis.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: November 13, 2014.

Julia Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2014–27538 Filed 11–20–14; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and deletions from the procurement list.

SUMMARY: This action adds products to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products from the Procurement List previously furnished by such agencies.

DATES: *Effective Date:* 12/22/2014.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 10800, 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 9/26/2014 (79 FR 57890–57891) and 10/10/2014 (79 FR 61296), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice 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 impact of the additions on the current or most recent contractors, the Committee has determined that the products 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 to the Government.

2. The action will result in authorizing small entities to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products are added to the Procurement List:

Products

NSN: 8520–00–NIB–0149—Refill, Instant Hand Sanitizer, Foam, Advanced Green Certified, 1200 ml

NSN: 8520–00–NIB–0150—Refill, Instant Hand Sanitizer, Foam, Skin Nourishing, Advanced Green Certified, 1200 ml

NSN: 8520–00–NIB–0151—Refill, Hand Soap, Foam, Anti-Bacterial, Plum Fragrance, Purple, Advanced Green Certified, 1250 ml

NSN: 8520–00–NIB–0152—Refill, Hand Soap/Shower Wash, Foam, Ginger Fragrance, Green, Advanced Green Certified 1250 ml

NPA: Travis Association for the Blind, Austin, TX

Contracting Activity: General Services Administration, Fort Worth, TX

Coverage: B-List for the Broad Government Requirement as aggregated by the General Services Administration, Fort Worth, TX.
NSN: MR 1082—Broom, Large, Angle
NSN: MR 1081—Brush, Toilet Bowl
NSN: MR 1071—Brush, Kitchen
NSN: MR 1070—Brush, Power Scrub
NSN: MR 1074—Broom, Corn
NPA: Alphapointe, Kansas City, MO
Contracting Activity: NEXCOM-Navy Exchange Service Command, Virginia Beach, VA
Coverage: C-List for the requirements of Navy Exchanges as aggregated by the Navy Exchange Service Command (NEXCOM), Virginia Beach, VA.
NSN: MR 10669—Kit, Party, New Year's
NPA: Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC
Contracting Activity: Defense Commissary Agency, Fort Lee, VA
Coverage: C-List for the requirements of military commissaries and exchanges as aggregated by the Defense Commissary Agency, Fort Lee, VA.

Deletions

On 10/17/2014 (79 FR 62417), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products deleted from the Procurement List.

End of Certification

Accordingly, the following products are deleted from the Procurement List:

Products

Clamp, Loop

NSN: 5340–00–410–6441—Cushion Type AMS3839
NSN: 5340–00–411–2953—Cushion Type AMS3839
NPA: Provail, Seattle, WA
Contracting Activity: Defense Logistics Agency Troop Support, Philadelphia, PA

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2014–27591 Filed 11–20–14; 8:45 am]

BILLING CODE 6353–01–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.

Comments Must Be Received On Or Before: 12/22/2014.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 10800, 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: 8415–00–FAB–5250—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, UCP, S–R
NSN: 8415–00–FAB–5295—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, UCP, L–R
NSN: 8415–00–FAB–5296—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, UCP, L–L
NSN: 8415–00–FAB–5293—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, UCP, M–R
NSN: 8415–00–FAB–5297—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, UCP, XL–R
NSN: 8415–00–FAB–5298—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, UCP, XL–L
NSN: 8415–00–FAB–5207—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, UCP, XS–S
NSN: 8415–00–FAB–5226—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, UCP, S–S
NSN: 8415–00–FAB–5251—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, UCP, S–L
NSN: 8415–00–FAB–5294—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, UCP, M–L
NSN: 8415–00–FAB–5299—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, UCP, XL–XL
NSN: 8415–00–FAB–5302—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, UCP, XXL–R
NSN: 8415–00–FAB–5301—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, UCP, XXL–L
NSN: 8415–00–FAB–5303—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, UCP, XXL–XL
NSN: 8415–00–FAB–5249—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, UCP, XS–R
NSN: 8415–00–FAB–0899—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, Multi-Cam, S–R
NSN: 8415–00–FAB–0897—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, Multi-Cam, M–R
NSN: 8415–00–FAB–0895—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, Multi-Cam, L–R
NSN: 8415–00–FAB–0894—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, Multi-Cam, L–L
NSN: 8415–00–FAB–0903—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, Multi-Cam, XL–R
NSN: 8415–00–FAB–0901—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, Multi-Cam, XL–L
NSN: 8415–00–FAB–0908—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, Multi-Cam, XS–S
NSN: 8415–00–FAB–0907—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, Multi-Cam, XS–R
NSN: 8415–00–FAB–0900—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, Multi-Cam, S–S
NSN: 8415–00–FAB–0898—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, Multi-Cam, S–L
NSN: 8415–00–FAB–0896—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, Multi-Cam, M–L
NSN: 8415–00–FAB–0905—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, Multi-Cam, XL–XL
NSN: 8415–00–FAB–0914—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, Multi-Cam, XXL–R

NSN: 8415–00–FAB–0912—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, Multi-Cam, XXL–L
NSN: 8415–00–FAB–0916—Kit, Pre-Cut Fabric, ECWCS Gen III Trouser, Multi-Cam, XXL–XL
NSN: 8415–00–TPE–0929—Tape, Seam, Pre-Cut component for ECWCS Gen III Trousers, Black
NPA: Blind Industries & Services of Maryland, Baltimore, MD
Contracting Activity: Department of Justice, Federal Prison System, Washington, DC
Coverage: C-List for 100% of the requirements of the Federal Prison Industries UNICOR, as aggregated by the Federal Prison System, Washington, DC.

Services

Service Type/Location: Grounds Maintenance Service, U.S. Coast Guard, Townsends Inlet Recreational Facility, 8101 Landis Avenue, Sea Isle City, NJ
NPA: Fedcap Rehabilitation Services, Inc., New York, NY
Contracting Activity: U.S. Coast Guard, Base Portsmouth, Portsmouth, VA

Deletions

The following products are proposed for deletion from the Procurement List:

Products

Microfibers Kitchen Towels and Cloths

NSN: MR 939—Set, Cleaning, Microfiber, Leaf Print, 2 Piece
NPA: Alphapointe, Kansas City, MO
Contracting Activity: Defense Commissary Agency, Fort Lee, VA

Disk, Flexible

NSN: 7045–01–283–4362—Disk, Flexible
NPA: North Central Sight Services, Inc., Williamsport, PA
Contracting Activity: Defense Logistics Agency Troop Support, Philadelphia, PA

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2014–27592 Filed 11–20–14; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 14–53]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Cooperation Agency Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittals 14–53 with attached transmittal and policy justification.

Dated: November 18, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

NOV 12 2014

The Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 14-53, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance to Iraq for defense articles and services estimated to cost $600 million. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Regional Balance (Classified Document Provided Under Separate Cover)

Transmittal No. 14–53

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Iraq

(ii) *Total Estimated Value:*

Major Defense Equipment *	$0 million
Other	$600 million
Total	$600 million

* As defined in Section 47(6) of the Arms Export Control Act.

(iii) *Description and Quantity or Quantities of Articles or Services Under Consideration for Purchase:* A Foreign Military Sales Order II (FMSO II) to provide funds for blanket order requisitions, under a Cooperative Logistics Supply Agreement (CLSSA) for spare parts to support M1A1 Battle Tanks, M1070 Heavy Equipment Tactical Trucks, M88A1/2 Tank Recovery Vehicles, M113 Vehicles, M198 Towed Howitzers, M109A5 Self Propelled Howitzers, High Mobility Multi-Purpose Wheeled Vehicles (HMMWV), Heavy Expanded Mobility Tactical Trucks (HEMTT), heavy and light machine guns, common repair sets, and additional authorized items with associated equipment and services.

(iv) *Military Department:* Army. (KAC, Amendment #1)

(v) *Prior Related Cases, if any:* FMS case KAC-$7M–12Feb13

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* None

(viii) *Date Report Delivered to Congress:* 12 Nov 2014

Policy Justification

Iraq—Foreign Military Sales Order II (FMSO II)

The Government of Iraq has requested a Foreign Military Sales Order II (FMSO II) to provide funds for blanket order requisitions, under a Cooperative Logistics Supply Agreement (CLSSA) for spare parts to support M1A1 Battle Tanks, M1070 Heavy Equipment Tactical Trucks, M88A1/2 Tank Recovery Vehicles, M113 Vehicles, M198 Towed Howitzers, M109A5 Self Propelled Howitzers, High Mobility Multi-Purpose Wheeled Vehicles (HMMWV), Heavy Expanded Mobility Tactical Trucks (HEMTT), heavy and light machine guns, common repair sets, and additional authorized items with associated equipment and services. The estimated cost is $600 million.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a strategic partner. This proposed sale directly supports the Government of Iraq and serves the interests of the people of Iraq and the United States.

Iraq requires continuing procurement and repair of spare parts through the U.S. Government's FMSO II program in order to maintain its military fleets of tanks, vehicles, and other associated equipment. The spare parts and repair sets to be procured under this proposed sale are critical for maintaining these ground transportation vehicles in operational condition.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be General Dynamics Land Systems in Sterling Heights, Michigan. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this sale will not require U.S. Government representatives or contractors to travel to Iraq.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2014–27601 Filed 11–20–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 14–35]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, DOD.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittals 14–35 with attached transmittal, policy justification, and Sensitivity of Technology.

Dated: November 18, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–O6–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

NOV 12 2014

Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 14-35, concerning the Department of the Navy's proposed Letter(s) of Offer and Acceptance to Iraq for defense articles and services estimated to cost $97 million. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

for J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified Document Provided Under Separate Cover)

BILLING CODE 5001–06–C

Transmittal No. 14–35

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Iraq

(ii) *Total Estimated Value:*

Major Defense Equipment *	$ 85 million.
Other	$ 12 million.
TOTAL	$ 97 million.

* As defined in Section 47(6) of the Arms Export Control Act.

(iii) *Description and Quantity or Quantities of Articles or Services Under Consideration for Purchase:* Up to 2,000 Advanced Precision Kill Weapon Systems, weapon and test support equipment, spare and repair parts, publications and technical documentation, personnel training and training equipment, transportation, U.S. Government and contractor engineering, technical and logistics support services, and other related elements of logistical and program support.

(iv) *Military Department:* Navy (AAB)

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* 12 Nov 2014

POLICY JUSTIFICATION

Iraq—Advanced Precision Kill Weapon System (APKWS)

The Government of Iraq has requested a possible sale of up to 2,000 Advanced Precision Kill Weapon Systems (APKWS), weapon and test support equipment, spare and repair parts, publications and technical documentation, personnel training and training equipment, transportation, U.S. Government and contractor engineering, technical and logistics support services, and other related elements of logistical and program support. The estimated cost is $97 million.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a strategic partner. This proposed sale directly supports the Government of Iraq and serves the interests of the people of Iraq and the United States.

The proposed sale will improve Iraq's capacity to sustain security operations and strengthen its internal and external defense capabilities. The sale of APKWS will increase the Iraqi Army Aviation Command's ability to carry out operations against terrorist forces while significantly reducing risk to civilians.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be BAE Systems in Nashua, New Hampshire. There are no known offset agreements proposed in connection with this potential sale.

The proposed sale will involve multiple trips to Iraq involving U.S. government and contractor representatives for approximately 3 years for program management, program and technical reviews, training, maintenance support, and site surveys.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 14–35

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) Sensitivity of Technology:

1. The APKWS II All-Up-Round (AUR) is an air-to-ground weapon that consists of an APKWS II Guidance Section (GS), legacy 2.75-inch MK66 Mod 4 rocket motor and legacy MK152 and MK435/436 warhead/fuze. The APKWS is a tactical rocket system that can be launched from several platforms, offering multi-mission, multi-target capability and precision-strike lethality. These guided rockets are steered to the target by following reflected laser beam energy directed onto the target either by the launching aircraft, a second aircraft, or ground-based troops operating a laser designator. Hardware is Unclassified; information related to performance, effectiveness, vulnerabilities and counter-measure is classified up to Secret.

2. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures that might reduce system effectiveness or be used in the development of a system with similar or advanced capabilities.

3. A determination has been made that the recipient country can provide the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification. Any defense articles or services offered under this notification will only be delivered if the recipient has appropriate storage, security, and procedures in place to properly protect those items.

4. All defense articles and services listed in this transmittal have been authorized for release and export to the Government of Iraq.

[FR Doc. 2014–27598 Filed 11–20–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 14–56]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601–3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 14–56 with attached transmittal, policy justification, and Sensitivity of Technology.

Dated: November 18, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–C

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

NOV 12 2014

The Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 14-56, concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance to Australia for defense articles and services estimated to cost $1.609 billion. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

for J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

Transmittal No. 14–56

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Australia

(ii) *Total Estimated Value:*

Major Defense Equipment *	$1.465 billion.
Other	$ .144 billion.
TOTAL	$1.609 billion.

* As defined in Section 47(6) of the Arms Export Control Act.

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* up to 4 C–17A GLOBEMASTER III aircraft, 19 F117–PW–100 Pratt & Whitney engines, 4 AN/AAQ–24V Large Aircraft Infrared Countermeasures (LAIRCM) Systems, 4 Small Laser Transmitter Assemblies, 4 System Processors, 4 AN/AAR–54 Missile Warning Sensors, 1 AN/ALE–47 Countermeasure Dispenser, 1 AN/AAR–47 Missile Warning System, 5 Trimble Force 524 Receivers, 2 GAS–1 Antenna Units, 2 Controlled Reception Pattern Antennas, 1 AN–USC–43V Advanced Narrowband Voice Terminal, 16 Honeywell H–764 ACE Embedded Global Positioning System/Inertial Navigation Systems, spare and repair parts, supply and test equipment, personnel training and training equipment, publications and technical documentation, United States Government and contractor engineering,

logistics, and technical support services, and other related elements of logistics support.

(iv) *Military Department:* Air Force (SAQ)

(v) Prior Related Cases, if any: FMS Case SEN–$1.2B–19May06, FMS Case SGT–$254M–6Apr11, FMS Case SGV–$275M–22Mar12.

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* 12 Nov 2014

POLICY JUSTIFICATION

Australia—C–17 Globemaster III Aircraft

The Government of Australia has requested a possible sale of up to 4 C–17A Globemaster III aircraft, 19 F117–PW–100 Pratt & Whitney engines, 4 AN/AAQ–24V Large Aircraft Infrared Countermeasures (LAIRCM) Systems, 4 Small Laser Transmitter Assemblies, 4 System Processors, 4 AN/AAR–54 Missile Warning Sensors, 1 AN/ALE–47 Countermeasure Dispenser, 1 AN/AAR–47 Missile Warning System, 5 Trimble Force 524 Receivers, 2 GAS–1 Antenna Units, 2 Controlled Reception Pattern Antennas, 1 AN–USC–43V Advanced Narrowband Voice Terminal, 16 Honeywell H–764 ACE Embedded Global Positioning System/Inertial Navigation Systems, spare and repair parts, supply and test equipment, personnel training and training equipment, publications and technical documentation, United States Government and contractor engineering, logistics, and technical support services, and other related elements of logistics support. The estimated cost for up to four C–17As, support and services is $1.609 billion.

This sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a major contributor to political stability, security, and economic development in Southeast Asia. Australia is an important ally and partner that contributes significantly to peacekeeping and humanitarian operations around the world. It is vital to the U.S. national interest to assist our ally in developing and maintaining a strong and ready self-defense capability. This proposed sale is consistent with those objectives and facilitates burden sharing with a key ally.

Australia's current heavy airlift capability consists of six C–17A aircraft. The proposed sale of additional C–17As will further improve Australia's capability to deploy rapidly in support of global coalition operations and will also greatly enhance its ability to lead regional humanitarian and peacekeeping operations. Australia has the ability to absorb and employ these additional C–17As into its inventory.

The proposed sale of these aircraft and support will not alter the basic military balance in the region.

The principal contractor will be the Boeing Company in Long Beach, California. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to Australia.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 14–56

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The Boeing C–17A Globemaster III military airlift aircraft is the most flexible cargo aircraft to enter the U.S. Air Force fleet. The C–17 is capable of rapid strategic delivery of up to 170,900 pounds of personnel and equipment to main operating bases or forward operating locations. The aircraft is also capable of short field landings with a full cargo load. The aircraft can perform tactical airlift and airdrop missions as well as transport litters and ambulatory patients during aeromedical evacuation when required. A fully integrated electronic cockpit and advanced cargo delivery system allow a crew of three: Pilot, copilot, and loadmaster, to operate the aircraft on any type of mission.

2. The AN/AAQ–24V(13) Large Aircraft Infrared Countermeasures (LAIRCM) is an active countermeasures system designed to defeat man-portable, shoulder-fired, and vehicle-launched infrared guided missile guidance systems by directing a high-intensity modulated laser beam into the missile seeker. This aircraft self-protection suite will provide fast, accurate threat detection, processing, tracking and countermeasures to defeat current and future generation infrared missile threats. LAIRCM is designed for installation on a wide range of fixed-wing aircraft.

3. The AN/ALE–47 Countermeasures Dispensing System (CMDS) is a integrated, threat-adaptive, software-programmable dispensing system capable of dispensing chaff, flares, and active radio frequency expendables. The threats countered by the CMDS include radar-directed anti-aircraft artillery (AAA), radar command-guided missiles, radar homing guided missiles, and infrared (IR) guided missiles. The system is internally mounted and may be operated as a stand-alone system or may be integrated with other on-board electronic warfare and avionics systems. The AN/ALE–47 uses threat data received over the aircraft interfaces to assess the threat situation and to determine a response. Expendable decoys tailored to the immediate aircraft and threat environment may be dispensed using one of four operational modes. The hardware, technical data, and documentation to be provided are Unclassified.

4. The Global Positioning System (GPS) Antenna System (GAS)–1 is a controlling unit that is part of the Controlled Reception Pattern Antenna (CRPA) system. The CRPA is part of the GPS tracking. The GAS–1 antenna provides basic anti-jam capability allowing operations to be carried out with greater accuracy and decreased risk.

5. The Advanced Narrowband Digital Voice Terminal (ANDVT) provides secure voice communications. These terminals are handled as unclassified controlled cryptographic items when un-keyed; when keyed, they assume the classification of the key. The ANDVT provides joint interoperability between Service components of U.S. command elements and North American Treaty Organization allies.

6. KYV–5 Communication Security Module enables secure voice for the ANDVT.

7. If a technologically advance adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures or equivalent systems with might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

8. A determination has been made that the Government of Australia can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

9. All defense articles and services listed in this transmittal have been

authorized for release and export to the Government of Australia.

[FR Doc. 2014–27605 Filed 11–20–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Termination of Department of Defense Federal Advisory Committees

AGENCY: DoD.

ACTION: Termination of Federal Advisory Committee.

SUMMARY: The Department of Defense is publishing this notice to announce that it is terminating the Department of Defense Task Force on the Care, Management, and Transition of Recovering Wounded, Ill, and Injured Members of the Armed Forces (''the Task Force'').

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703–692–5952.

SUPPLEMENTARY INFORMATION: This committee is being terminated in accordance with section 724 of Public Law 111–84(f) and under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C. Appendix), 41 CFR 102–3.55, and the Government in the Sunshine Act of 1976 (5 U.S.C. 552b), effective October 27, 2014.

Dated: November 18, 2014.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2014–27593 Filed 11–20–14; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Educational Technology, Media, and Materials for Individuals With Disabilities—Stepping-up Technology Implementation

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

Overview Information

Educational Technology, Media, and Materials for Individuals with Disabilities—Stepping-up Technology Implementation.

Notice inviting applications for new awards for fiscal year (FY) 2015.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.327S.

DATES: Applications Available: November 21, 2014.

Deadline for Transmittal of Applications: January 20, 2015.

Deadline for Intergovernmental Review: March 23, 2015.

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purposes of the Educational Technology, Media, and Materials for Individuals with Disabilities Program are to: (1) Improve results for students with disabilities by promoting the development, demonstration, and use of technology; (2) support educational activities designed to be of educational value in the classroom for students with disabilities; (3) provide support for captioning and video description that is appropriate for use in the classroom; and (4) provide accessible educational materials to students with disabilities in a timely manner.

Priority: In accordance with 34 CFR 75.105(b)(2)(v), this priority is from allowable activities specified in the statute (see sections 674 and 681(d) of the Individuals with Disabilities Education Act (IDEA) (20 U.S.C. 1400 *et seq.*)).

Absolute Priority: For FY 2015 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet this priority.

This priority is:

Educational Technology, Media, and Materials for Individuals with Disabilities—Stepping-up Technology Implementation.

Background: The purpose of this priority is to fund cooperative agreements to: (a) Identify strategies needed to effectively implement evidence-based [1] technology tools [2] that benefit students with disabilities; and (b) develop and

[1] For the purposes of this priority, the definition of ''evidence-based'' consists of the following definitions in 34 CFR 77.1: *Large sample* means an analytic sample of 350 or more students (or other single analysis units) who were randomly assigned to a treatment or control group or 50 or more groups (such as classrooms or schools) that contain 10 or more students (or other single analysis units) and that were randomly assigned to a treatment or control group. *Moderate evidence of effectiveness* means one of the following conditions is met:

(i) There is at least one study of the effectiveness of the process, product, strategy, or practice being proposed that meets the What Works Clearinghouse Evidence Standards without reservations [What Works Clearinghouse Procedures and Standards Handbook (Version 2.1, September 2011), which can currently be found at the following link: *http://ies.ed.gov/ncee/wwc/DocumentSum.aspx?sid=19*], found a statistically significant favorable impact on a relevant outcome (with no statistically significant and overriding unfavorable impacts on that outcome for relevant populations in the study or in other studies of the intervention reviewed by and reported on by the What Works Clearinghouse), and includes a sample that overlaps with the populations or settings proposed to receive the process, product, strategy, or practice.

(ii) There is at least one study of the effectiveness of the process, product, strategy, or practice being proposed that meets the What Works Clearinghouse Evidence Standards with reservations [What Works Clearinghouse Procedures and Standards Handbook (Version 2.1, September 2011), which can currently be found at the following link: *http://ies.ed.gov/ncee/wwc/DocumentSum.aspx?sid=19*], found a statistically significant favorable impact on a relevant outcome (with no statistically significant and overriding unfavorable impacts on that outcome for relevant populations in the study or in other studies of the intervention reviewed by and reported on by the What Works Clearinghouse), includes a sample that overlaps with the populations or settings proposed to receive the process, product, strategy, or practice, and includes a large sample and a multi-site sample (Note: Multiple studies can cumulatively meet the large and multi-site sample requirements as long as each study meets the other requirements in this paragraph).

Multi-site sample means more than one site, where site can be defined as an LEA, locality, or State.

Relevant outcome means the student outcome or outcomes (or the ultimate outcome if not related to students) that the proposed process, product, strategy, or practice is designed to improve, consistent with the specific goals of a program. *Strong evidence of effectiveness* means that one of the following conditions is met:

(i) There is at least one study of the effectiveness of the process, product, strategy, or practice being proposed that meets the What Works Clearinghouse Evidence Standards without reservations [What Works Clearinghouse Procedures and Standards Handbook (Version 2.1, September 2011), which can currently be found at the following link: *http://ies.ed.gov/ncee/wwc/DocumentSum.aspx?sid=19*], found a statistically significant favorable impact on a relevant outcome (with no statistically significant and overriding unfavorable impacts on that outcome for relevant populations in the study or in other studies of the intervention reviewed by and reported on by the What Works Clearinghouse), includes a sample that overlaps with the populations and settings proposed to receive the process, product, strategy, or practice, and includes a large sample and a multi-site sample (Note: Multiple studies can cumulatively meet the large and multi-site sample requirements as long as each study meets the other requirements in this paragraph).

(ii) There are at least two studies of the effectiveness of the process, product, strategy, or practice being proposed, each of which: Meets the What Works Clearinghouse Evidence Standards with reservations [What Works Clearinghouse Procedures and Standards Handbook (Version 2.1, September 2011), which can currently be found at the following link: *http://ies.ed.gov/ncee/wwc/DocumentSum.aspx?sid=19*], found a statistically significant favorable impact on a relevant outcome (with no statistically significant and overriding unfavorable impacts on that outcome for relevant populations in the studies or in other studies of the intervention reviewed by and reported on by the What Works Clearinghouse), includes a sample that overlaps with the populations and settings proposed to receive the process, product, strategy, or practice, and includes a large sample and a multi-site sample.

[2] For the purposes of this priority, ''technology tools'' may include, but are not limited to, digital math text readers for students with visual

disseminate products [3] that will help a broad range of schools to effectively implement these technology tools. As Congress recognized in IDEA, ''almost 30 years of research and experience has demonstrated that the education of children with disabilities can be made more effective by . . . supporting the development and use of technology, including assistive technology devices and assistive technology services, to maximize accessibility for children with disabilities'' (section 601(c)(5)(H) of IDEA).

The use of technology, including assistive technology devices and assistive technology services, enhances instruction and access to the general education curriculum. Technology can be the great equalizer in a classroom for students with disabilities. Whereas teachers can find it difficult to differentiate instruction for a large number of students in one class, all with different needs and abilities, technology tools that benefit students with disabilities can often help teachers personalize lessons and skill building for each child. ''Most students with disabilities can and do benefit from technology in the classroom. Incorporating technology increases students' motivation to learn and personalizes lessons to a student's individual needs'' (Zorigian & Job, 2008). Furthermore, technologies offer opportunities to support State educational agency (SEA) and local educational agency (LEA) Elementary and Secondary Education Act (ESEA) flexibility plans by: (a) Improving student learning and engagement; (b) accommodating the special needs of students; (c) facilitating student and teacher access to digital content and resources; [4] and (d) improving the quality of instruction through personalized learning and data (Duffey & Fox, 2012; Fletcher, Schaffhauser, & Levi, 2012; U.S. Department of Education, 2010).

Employing products and resources designed to assist with the implementation of evidence-based technology tools is critical to ensuring that these tools will be effectively used to improve early childhood outcomes, academic achievement, and college- and career-readiness of children with disabilities. Data from a survey of more than 1,000 kindergarten through grade 12 (K–12) teachers, principals, and assistant principals indicated that simply providing teachers with technology does not ensure that it will be used. The survey also indicated that while newer teachers may use technology in their personal lives more often than veteran teachers, they do not use it more frequently in their classrooms than veteran teachers do. The survey also revealed that the more often teachers use technology to improve students' daily classroom engagement, the more likely teachers are to recognize the benefits to understanding different student learning styles (Grunwald Associates, 2010). Additionally, Perlman and Redding (2011) found that in order to be used most effectively, technology must be implemented in ways that align with curricular and teacher goals and must offer students opportunities to use these tools in their learning. While for years there has been a vast improvement in the infrastructure to support the implementation of technology in educational institutions, the integration of technology at all levels still remains surprisingly low (Lu & Overbaugh, 2009). For example, even as many systems have recently been deployed to deliver coursework online and the number of students involved in online learning has grown precipitously, many of these online learning technologies have not been designed to be accessible to students with disabilities (Center on Online Learning and Students with Disabilities, 2012). These findings demonstrate a need for products and resources that can ensure technology tools for students with disabilities are implemented effectively.

Since 1998, the Office of Special Education Programs (OSEP) has supported technology and media service projects through the Steppingstones of Technology Innovation for Children with Disabilities (Steppingstones) program. The projects funded under the Steppingstones program developed and evaluated numerous innovative technology tools designed to improve results for children with disabilities. Examples of such tools include: Web-based learning and assessment materials, instructional software, assistive technology devices, methods for using off-the-shelf hardware and software to improve learning, and methods for integrating technology into instruction. In addition, the Department's Institute of Education Sciences (IES) now supports projects to develop and evaluate innovative technology tools. The Stepping-up Technology Implementation program is building on these technology development efforts by identifying, developing, and disseminating products and resources that promote the effective implementation [5] of evidence-based instructional and assistive technology tools in early childhood or K–12 settings.[6]

Priority: The purpose of this priority is to fund cooperative agreements to: (a) Identify strategies needed to effectively implement evidence-based technology tools that benefit students with disabilities; and (b) develop and disseminate products (e.g., instruction manuals, lesson plans, demonstration videos, ancillary instructional materials) that will help early childhood or K–12 settings to effectively implement these technology tools.

To be considered for funding under this absolute priority, applicants must meet the application requirements. Any project funded under this absolute priority must also meet the programmatic and administrative requirements specified in the priority.

Application Requirements: An applicant must include in its application—

(a) A logic model or conceptual framework that depicts at a minimum, the goals, activities, outputs, and outcomes of the proposed project. A logic model communicates how a project will achieve its outcomes and provides a framework for both formative and summative evaluations of the project;

Note: The following Web sites provide more information on logic models: *www.researchutilization.org/matrix/logicmodel_resource3c.html* and *www.tadnet.org/pages/589.*

(b) A plan to implement the activities described in the *Project Activities* section of this priority;

(c) A plan, linked to the proposed project's logic model, for a formative evaluation of the proposed project's activities. The plan must describe how

impairment, reading software to improve literacy and communication development, and text-to-speech software to improve reading performance. These tools must assist or otherwise benefit students with disabilities.

[3] For the purposes of this priority, ''products'' may include, but are not limited to, instruction manuals, lesson plans, demonstration videos, ancillary instructional materials, and professional development modules such as collaborative groups, coaching, mentoring, or online supports.

[4] For the purposes of this priority, ''resources'' include, but are not limited to, school leadership support, professional development support to school staff, and a plan for integrating technology into the classroom curriculum.

[5] In this context, ''effective implementation'' means ''making better use of research findings in typical service settings through the use of processes and activities (such as accountable implementation teams) that are purposeful and described in sufficient detail such that independent observers can detect the presence and strength of these processes and activities'' (Fixsen, Naoom, Blase, Friedman, & Wallace, 2005).

[6] For the purposes of this priority, ''settings'' include general education classrooms, special education classrooms or any place where school-based instruction occurs.

the formative evaluation will use clear performance objectives to ensure continuous improvement in the operation of the proposed project, including objective measures of progress in implementing the project and ensuring the quality of products and services;

(d) A plan for recruiting and selecting the following:

(1) Three development schools. Development schools are the sites in which iterative development [7] of the implementation of technology tools and products will occur. The project must start implementing the technology tool with one development school in year one of the project period and two additional development schools in year two.

(2) Four pilot schools. Pilot schools are the sites in which try-out, formative evaluation, and refinement of technology tools and products will occur. The project must work with the four pilot schools during years three and four of the project period.

(3) Ten dissemination schools. Dissemination schools will be selected if the project is extended for a fifth year. Dissemination schools will be used to conduct the final test of the effectiveness of the products and the final opportunity for the project to refine the products for use by teachers, but will receive less technical assistance (TA) from the project than the development or pilot schools. Also, at this stage, dissemination schools will extend the benefits of the technology tool to additional students. To be selected as a dissemination school, eligible schools and LEAs must commit to working with the project to implement the evidence-based technology tool. A school may not serve in more than one category (i.e., development, pilot, dissemination).

(e) Information (e.g., early childhood setting; elementary, middle, or high school; persistently lowest-achieving school; [8] priority school [9]) about the diversity of the development, pilot, and dissemination schools; their demographics (e.g., student race or ethnicity, percentage of students eligible for free or reduced-price lunch); and other pertinent data.

(f) Documentation that the technology tool is evidence-based (as defined in this notice) and that it can be implemented to improve early childhood outcomes, academic achievement, and college- and career-readiness.

(g) A budget for attendance at the following:

(1) A one and one-half day kick-off meeting to be held in Washington, DC, after receipt of the award, and an annual planning meeting held in Washington, DC, with the OSEP project officer and other relevant staff during each subsequent year of the project period.

Note: Within 30 days of receipt of the award, a post-award teleconference must be held between the OSEP project officer and the grantee's project director or other authorized representative.

(2) A three-day project directors' conference in Washington, DC, during each year of the project period.

(3) Two two-day trips annually to attend Department briefings, Department-sponsored conferences, and other meetings, as requested by OSEP.

Project Activities. To meet the requirements of this priority, the project, at a minimum, must conduct the following activities:

(a) Recruit a minimum of three development schools in one LEA and four pilot schools across at least two LEAs in accordance with the plan proposed under paragraph (d) of the *Application Requirements* section of this notice.

Note: Final site selection will be determined in consultation with the OSEP project officer following the kick-off meeting.

(b) Identify resources and develop products to support sustained implementation of the selected technology tool. Development of the products must be an interactive process beginning in a single development school and continuing through iterative cycles of development and refinement in the other development schools, followed by a formative evaluation and refinement in the pilot schools. The products must include, at a minimum, the following components to support implementation of the technology tool:

(1) An instrument or method for assessing (i) the need for the technology tool, and (ii) readiness to implement it. Instruments and methods may include resource inventory checklists, school self-study guides, surveys of teacher interest, detailed descriptions of the technology tool for review by school staff, and similar approaches used singly or in combination.

(2) Methods and manuals to support the implementation of the technology tool.

(3) Professional development activities necessary for teachers to implement the technology tool with fidelity and integrate it into the curriculum.

(c) Collect and analyze data on the effect of the technology tool on academic achievement and college- and career-readiness.

(d) Collect formative and summative evaluation data from the development schools and pilot schools to refine and evaluate the products.

(e) If the project is extended to a fifth year, provide the products and the technology tool to no fewer than 10 dissemination schools that are not the same schools used as development and pilot schools.

(f) Collect summative data about the success of the products in supporting

[7] For the purposes of this priority, ''iterative development'' refers to a process of testing, systematically securing feedback, and then revising the educational intervention that leads to revisions in the intervention to increase the likelihood that it will be implemented with fidelity (Diamond & Powell, 2011).

[8] The term ''persistently lowest-achieving schools'' means, as determined by the State—

(a)(1) Any Title I school in improvement, corrective action, or restructuring that—

(i) 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

(ii) 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—

(i) 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

(ii) 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 persistently lowest-achieving schools, a State must take into account both—

(i) 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 Elementary and Secondary Education Act of 1965, as amended (ESEA) in reading/language arts and mathematics combined; and

(ii) The school's lack of progress on those assessments over a number of years in the ''all students'' group.

For the purposes of this priority, the Department considers schools that are identified as Tier I or Tier II schools under the School Improvement Grants Program (see 75 FR 66363) as part of a State's approved FY 2009, FY 2010, FY 2011, or FY 2012 application to be persistently lowest-achieving schools. A list of these Tier I and Tier II schools can be found on the Department's Web site at *www2.ed.gov/programs/sif/index.html.*

[9] The term ''priority school'' means a school that has been identified by the State as a priority school pursuant to the State's approved request for ESEA flexibility.

implementation of the technology tool in the dissemination schools; and

(g) By the end of the project period, projects must provide information on:

(1) The products and resources that will enable other schools to implement and sustain implementation of the technology tool.

(2) How the technology tool has improved early childhood, academic achievement, or college- and career-readiness for children with disabilities.

(3) A strategy for disseminating the technology tool and accompanying products beyond the schools directly involved in the project.

Cohort Collaboration and Support.

OSEP Project Officer(s) will provide coordination support among the projects. Each project funded under this priority must—

(a) Participate in bi-monthly conference call discussions to share and collaborate around implementation and specific project issues,

(b) Provide information bi-annually using a template that captures descriptive data on project site selection, processes for installation of technology, and the use of technology and sustainability (i.e., the process of technology implementation).

Note: The following Web site provides more information about implementation research: *http://nirn.fpg.unc.edu/learn-implementation.*

Fifth Year of the Project: The Secretary may extend a project one year beyond 48 months to work with dissemination schools if the grantee is achieving the intended outcomes and making a positive contribution to the implementation of an evidence-based technology tool in the development and pilot schools. Each applicant must include in its application a plan for the full 60-month award. In deciding whether to continue funding the project for the fifth year, the Secretary will consider the requirements of 34 CFR 75.253(a), and in addition—

(a) The recommendation of a review team consisting of the OSEP project officer and other experts selected by the Secretary. This review will be held during the last half of the third year of the project period;

(b) The timeliness and effectiveness with which all requirements of the negotiated cooperative agreement have been or are being met by the project; and

(c) Evidence of the degree to which the project's activities have contributed to changed practices and improved early childhood outcomes, academic achievement, or college- and career-readiness for students with disabilities.

Competitive Preference Priority: Within this absolute priority, we give competitive preference to applications that meet the following priority. For FY 2015 and any subsequent year in which we make awards from the list of unfunded applicants from this competition, this priority is a competitive preference priority.

This priority is from the notice of final supplemental priorities and definitions for discretionary grant programs, published in the **Federal Register** on December 15, 2010 (75 FR 78486), and corrected on May 12, 2011 (76 FR 27637).

Under 34 CFR 75.105(c)(2)(i) we award an additional five points to an application that meets this priority.

This priority is:

Enabling More Data-Based Decision-Making.

Projects that are designed to collect (or obtain), analyze, and use high-quality and timely data, including data on program participant outcomes, in accordance with privacy requirements,[10] in one or more of the following priority areas:

(a) Improving instructional practices, policies, and child outcomes in early learning settings.

(b) Improving instructional practices, policies, and student outcomes in elementary or secondary schools.

(c) Improving postsecondary student outcomes relating to enrollment, persistence, and completion and leading to career success.

(d) Providing reliable and comprehensive information on the implementation of Department of Education programs, and participant outcomes in these programs by using data from State longitudinal data systems or by obtaining data from reliable third-party sources.

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Waiver of Proposed Rulemaking: Under the Administrative Procedure Act (APA) (5 U.S.C. 553) the Department generally offers interested parties the opportunity to comment on proposed priorities and requirements. Section 681(d) of IDEA, however, makes the public comment requirements of the APA inapplicable to the priorities in this notice.

Program Authority: 20 U.S.C. 1474 and 1481.

Applicable Regulations: This application notice (also referred to as a notice inviting applications (NIA)) is being published before the Department adopts the Uniform Administrative Requirements, Cost Principles, and Audit Requirements in 2 CFR part 200. We expect to publish interim final regulations that would adopt those requirements before December 26, 2014, and make those regulations effective on that date. Because grants awarded under this NIA will likely be made after the

[10] ''Privacy requirements'' means the requirements of the Family Educational Rights and Privacy Act (FERPA), 20 U.S.C. 1232g, and its implementing regulations in 34 CFR part 99, the Privacy Act, 5 U.S.C. 552a, as well as all applicable Federal, State and local requirements regarding privacy.

Department adopts the requirements in 2 CFR part 200, we list as applicable regulations both those that are currently effective and those that will be effective at the time the Department makes grants.

The current regulations follow: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 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.

At the time we award grants under this NIA, the following regulations will apply: (a) EDGAR in 34 CFR parts 75, 77, 79, 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, and 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.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education (IHEs) only.

II. Award Information

Type of Award: Cooperative Agreements.

Estimated Available Funds: The Administration has requested $28,047,000 for the Educational Technology, Media, and Materials for Individuals with Disabilities program for FY 2015, of which we intend to use an estimated $1,000,000 for this competition. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Contingent upon the availability of funds and the quality of applications, we may make additional awards in FY 2016 from the list of unfunded applicants from this competition.

Estimated Range of Awards: $475,000 to $500,000 per year.

Estimated Average Size of Awards: $500,000 per year.

Maximum Award: We will reject any application that proposes a budget exceeding $500,000 for a single budget period of 12 months. The Assistant Secretary for Special Education and Rehabilitative Services may change the maximum amount through a notice published in the **Federal Register**.

Estimated Number of Awards: 2.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 48 months with an optional additional 12 months based on performance. Applications must include plans for both the 48 month award and the 12 month extension.

III. Eligibility Information

1. *Eligible Applicants:* SEAs; LEAs, including public charter schools that are considered LEAs under State law; IHEs; other public agencies; private nonprofit organizations; outlying areas; freely associated States; Indian tribes or tribal organizations; and for-profit organizations.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. *Other General Requirements:*

(a) Recipients of funding under this program must make positive efforts to employ and advance in employment qualified individuals with disabilities (see section 606 of IDEA).

(b) Each applicant for, and recipient of, funding under this competition must involve individuals with disabilities, or parents of individuals with disabilities ages birth through 26, in planning, implementing, and evaluating the project (see section 682(a)(1)(A) of IDEA).

IV. Application and Submission Information

1. *Address to Request Application Package:* You 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.ed.gov/fund/grant/apply/grantapps/index.html*. 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 from ED Pubs, be sure to identify this competition as follows: CFDA number 84.327S.

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 or team listed under *Accessible Format* in section VIII of this notice.

2. *Content and Form of Application Submission:* Requirements concerning the content of an application, together with the forms you must submit, are in the application package for this competition.

Page Limit: The application narrative (Part III of the application) is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. You must limit Part III to no more than 50 pages, using the following standards:

- A ''page'' is 8.5″ × 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, reference citations, and captions, as well as all text in charts, tables, figures, graphs, and screen shots.
- Use a font that is 12 point or larger.
- 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 and double-spacing 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 abstract (follow the guidance provided in the application package for completing the abstract), the table of contents, the list of priority requirements, the resumes, the reference list, the letters of support, or the appendices. However, the page limit and double-spacing does apply to all of Part III, the application narrative, including all text in charts, tables, figures, graphs, and screen shots.

We will reject your application if you exceed the page limit in the application narrative section; or if you apply standards other than those specified in the application package.

3. *Submission Dates and Times:* Applications Available: November 21, 2014.

Deadline for Transmittal of Applications: January 20, 2015.

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 section IV. 7. *Other Submission Requirements* of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

Deadline for Intergovernmental Review: March 23, 2015.

4. *Intergovernmental Review:* This competition 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:* 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) (formerly the Central Contractor Registry (CCR)), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active 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. 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 2–5 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 entered into the SAM database by an entity. 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, you will need to allow 24 to 48 hours for the information to be available in Grants.gov and before you can 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: *http://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 Stepping-up Technology Implementation competition, CFDA number 84.327S, 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 the Stepping-up Technology Implementation competition 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 84.327, not 84.327S).

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.*

• 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 PDF (Portable Document) read-only, non-modifiable format. Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF or submit a password-protected file, we will not review that material. Additional, detailed information on how to attach files is in the application instructions.

• Your electronic application must comply with any page-limit requirements described in this notice.

• After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. (This notification indicates receipt by Grants.gov only, not receipt by the Department.) The Department then will retrieve your application from Grants.gov and send a second notification to you by email. This second notification indicates that the Department has received your application and has assigned your application a PR/Award number (an ED-specified identifying number unique to your application).

• We may request that you provide us original signatures on forms at a later date.

Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System: If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1–800–518–4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that that problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. The Department will contact you after a determination is made on whether your application will be accepted.

Note: The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

Exception to Electronic Submission Requirement: You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

• You do not have access to the Internet; or

• You do not have the capacity to upload large documents to the Grants.gov system;

and

• No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevent you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Terry Jackson, U.S. Department of Education, 400 Maryland Avenue SW., Room 4081, Potomac Center Plaza (PCP), Washington, DC 20202–2600. FAX: (202) 245–7617.

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 84.327S), LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202–4260.

You must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

If your application is postmarked after the application deadline date, we will not consider your application.

Note: The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

c. *Submission of Paper Applications by Hand Delivery.*

If you qualify for an exception to the electronic submission requirement, you (or a courier service) may deliver your paper application to the Department by hand. You must deliver the original and two copies of your application by hand, on or before the application deadline date, to the Department at the following address: U.S. Department of Education, Application Control Center, Attention: (CFDA Number 84.327S), 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. *Selection Criteria:* The selection criteria for this program are from 34 CFR 75.210 and are listed in the application package.

2. *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 also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department of Education (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

3. *Additional Review and Selection Process Factors:* In the past, the Department has had difficulty finding peer reviewers for certain competitions because so many individuals who are eligible to serve as peer reviewers have conflicts of interest. The standing panel requirements under section 682(b) of IDEA also have placed additional constraints on the availability of reviewers. Therefore, the Department has determined that for some discretionary grant competitions, applications may be separated into two or more groups and ranked and selected for funding within specific groups. This procedure will make it easier for the Department to find peer reviewers by ensuring that greater numbers of individuals who are eligible to serve as reviewers for any particular group of applicants will not have conflicts of interest. It also will increase the quality, independence, and fairness of the review process, while permitting panel members to review applications under discretionary grant competitions for which they also have submitted applications. However, if the Department decides to select an equal number of applications in each group for funding, this may result in different cut-off points for fundable applications in each group.

4. *Special Conditions:* Under current 34 CFR 74.14 and 80.12 and, when grants are made under this NIA, 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 34 CFR parts 74 or 80, as applicable or, when grants are awarded, the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); 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 multi-year award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. 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 Department has established a set of performance measures, including long-term measures, that are designed to yield information on various aspects of the effectiveness and quality of the Educational Technology, Media, and Materials for Individuals with Disabilities program. These measures are included in the application package and focus on the extent to which projects are of high quality, are relevant to improving outcomes of children with disabilities, contribute to improving outcomes for children with disabilities, and generate evidence of validity and availability to appropriate populations. Projects funded under this competition are required to submit data on these measures as directed by OSEP:

Program Performance Measure #1: The percentage of educational technology, media, and materials projects judged to be of high quality.

Program Performance Measure #2: The percentage of educational technology, media, and materials projects judged to be of high relevance to improving outcomes of infants, toddlers, children, and youth with disabilities.

Program Performance Measure #3: The percentage of educational technology, media, and materials projects that produce findings, products, and other services that contribute to improving results for infants, toddlers, children, and youth with disabilities.

Program Performance Measure #4: The percentage of educational technology, media, and materials projects that validate their products and services.

Program Performance Measure #5: The percentage of educational technology, media, and materials projects that make validated technologies available for widespread use.

Grantees will be required to report information on their project's performance in annual performance reports and additional performance data

to the Department (34 CFR 75.590 and 75.591).

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 grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Agency Contact

FOR FURTHER INFORMATION CONTACT: Terry Jackson, U.S. Department of Education, 400 Maryland Avenue SW., Room 4081, PCP, Washington, DC 20202–2600. Telephone: (202) 245–6039.

If you use a TDD or a TTY, call the Federal Relay Service (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) by contacting the Grants and Contracts Services Team, U.S. Department of Education, 400 Maryland Avenue SW., Room 5075, PCP, Washington, DC 20202–2550. Telephone: (202) 245–7363. If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

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 Adobe Portable Document Format (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: November 17, 2104.

Michael K. Yudin,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 2014–27516 Filed 11–20–14; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RD14–13–000]

Commission Information Collection Activities (FERC–725F); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC–725F (Mandatory Reliability Standard for Nuclear Plant Interface Coordination: Reliability Standard NUC–001–3).

DATES: Comments on the collection of information are due January 20, 2015.

ADDRESSES: You may submit comments (identified by Docket No. RD14–13–000) by either of the following methods:

- eFiling at Commission's Web site: *http://www.ferc.gov/docs-filing/efiling.asp*
- Mail/Hand Delivery/Courier: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free), or (202) 502–8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663, and fax at (202) 273–0873.

SUPPLEMENTARY INFORMATION:

Title: FERC–725F (Mandatory Reliability Standard for Nuclear Plant Interface Coordination: Reliability Standard NUC–001–3).

OMB Control No.: 1902–0249.

Type of Request: Three-year extension of the FERC–725F information collection requirements with no changes to the current reporting requirements.

Abstract: The Commission requires the information collected by the FERC–725F to implement the statutory provisions of section 215 of the Federal Power Act (FPA) (16 U.S.C. 824o). On August 8, 2005, the Electricity Modernization Act of 2005, which is Title XII, Subtitle A, of the Energy Policy Act of 2005 (EPAct 2005), was enacted into law.[1] EPAct 2005 added a new section 215 to the FPA, which required a Commission-certified Electric Reliability Organization (ERO) to develop mandatory and enforceable Reliability Standards, which are subject to Commission review and approval. Once approved, the Reliability Standards may be enforced by the ERO subject to Commission oversight, or the Commission can independently enforce Reliability Standards.[2]

On February 3, 2006, the Commission issued Order No. 672, implementing section 215 of the FPA.[3] Pursuant to Order No. 672, the Commission certified one organization, North American Electric Reliability Corporation (NERC), as the ERO. The Reliability Standards developed by the ERO and approved by the Commission apply to users, owners and operators of the Bulk-Power System as set forth in each Reliability Standard.

On November 19, 2007, NERC filed its petition for Commission approval of the Nuclear Plant Interface Coordination Reliability Standard, designated NUC–001–1. In Order No. 716 the Commission approved the standard while also directing certain revisions.[4] Reliability Standard, NUC–001–2, was approved by the Commission January 21, 2010.[5] Revised Reliability Standard,

[1] Energy Policy Act of 2005, Public Law 109–58, Title XII, Subtitle A, 119 Stat. 594, 941 (2005), 16 U.S.C. 824o.

[2] 16 U.S.C. 824o(e)(3).

[3] *Rules Concerning Certification of the Electric Reliability Organization; and Procedures for the Establishment, Approval, and Enforcement of Electric Reliability Standards,* Order No. 672, FERC Stats. & Regs. ¶ 31,204, *order on reh'g,* Order No. 672–A, FERC Stats. & Regs. ¶ 31,212 (2006).

[4] *Mandatory Reliability Standard for Nuclear Plant Interface Coordination,* Order No. 716, 125 FERC ¶ 61,065, at P 189 & n.90 (2008), *order on reh'g,* Order No. 716–A, 126 FERC ¶ 61,122 (2009).

[5] *North American Electric Reliability Corporation,* 130 FERC ¶ 61,051 (2010). When the revised

NUC–001–3, was filed with the Commission by NERC on September 15, 2014.

The purpose of Reliability Standard NUC–001–3 is to require ''coordination between nuclear plant generator operators and transmission entities for the purpose of ensuring nuclear plant safe operation and shutdown.'' [6] Reliability Standard NUC–001–3 applies to nuclear plant generator operators (generally nuclear power plant owners and operators, including licensees) and ''transmission entities,'' defined in the Reliability Standard as including a nuclear plant's suppliers of off-site power and related transmission and distribution services. Reliability Standard NUC–001–3 requires a nuclear power plant operator and its suppliers of back-up power and related transmission and distribution services to coordinate concerning nuclear licensing requirements for safe nuclear plant operation and shutdown and system operating limits. Information collection requirements include establishing and maintaining interface agreements, including record retention requirements.

Type of Respondents: Nuclear operators, nuclear plants, transmission entities.

Estimate of Annual Burden [7] *:* The Commission estimates for the annual public reporting burden for the information collection are unchanged from the public notice issued for Reliability Standard NUC–001–2 on 10/30/2014 [8] in Docket No. IC14–16–000. Reliability Standard NUC–001–3 represents the implementation of recommendations made by the NERC Five Year Review Team to revise Reliability Standard NUC–001–2. These recommendations include clarifying and conforming changes to update the standard for current use of terminology implemented in other area of the Reliability Standards, as well as updated Violation Risk Factors and Violation Severity Levels for the evaluation of violations of the Reliability Standard. The burden of complying with the requirements under Reliability Standard NUC–001–3 will not change as the changes from the previous Reliability Standard NUC–001–2 are substantially administrative in nature.

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: November 13, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–27549 Filed 11–20–14; 8:45 am]

BILLING CODE 6717–01–P

Reliability Standard was approved the Commission did not go to OMB for approval. It is assumed that the changes made did not substantively affect the information collection and therefore a formal submission to OMB was not needed.

[6] *See* Reliability Standard NUC–001–3 at *http://www.nerc.com/files/NUC-001-3.pdf.*

[7] The Commission defines burden as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, reference 5 Code of Federal Regulations 1320.3.

[8] Published in the **Federal Register** at 79 FR 61068.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP14–545–000]

Texas Eastern Transmission, LP; Notice of Intent To Prepare an Environmental Assessment for the Proposed Bailey East Mine Panel 2l Project and Request for Comments on Environmental Issues

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Bailey East Mine Panel 2L Project in Docket No. CP14–545–000 (project). The project involves the excavation, abandonment, replacement, temporary elevation, and reburial of pipeline facilities currently operated by Texas Eastern Transmission, LP (Texas Eastern) in Greene County, Pennsylvania to facilitate the underground longwall mining of coal. The Commission will use this EA in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the project. Your input will help the Commission staff determine what issues they need to evaluate in the EA. Please note that the scoping period will close on December 17, 2014.

You may submit comments in written form. The details on how to submit written comments are in the Public Participation section of this notice.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of the proposed project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of a temporary easement to abandon, replace, elevate and monitor the proposed activities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the project, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

Texas Eastern provided landowners with a fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' This fact sheet addresses a number of typically-asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is also available for viewing on the FERC Web site (*www.ferc.gov*).

Summary of the Proposed Project

Texas Eastern is seeking authorization from the FERC pursuant to Sections 7(b) and 7(c) of the Natural Gas Act for the project, which includes work to be performed for the planned longwall coal mining activities of CONSOL Energy, Inc. (CONSOL) in Panel 2L of its Bailey East Mine. Texas Eastern designed the project to ensure the safe and efficient operation of its existing pipeline facilities at their certificated design capacities during the planned longwall mining activities which include mining coal below the pipelines and then allowing the mine roof to collapse after removing the mine braces.

Texas Eastern proposes to excavate and elevate sections of Lines 10, 15, and 25 totaling about 7,726 feet in length over Panel 2L to monitor and mitigate potential strains and stresses on these pipeline sections. Texas Eastern would also replace with like-diameter pipeline the excavated segments of Lines 10, 15, and 25 during pipe elevation. Also,

Texas Eastern would conduct maintenance on Line 30 and would install a temporary 2,735-foot-long section of pipeline above-ground to ensure continued service from Line 30 during mining.

The four mainline segments would remain elevated using sandbags and skids for about 2 years until the longwall mining activities have been completed and the area is allowed time to settle. During the actual subsidence event, all segments would be monitored with strain gauges, and adjustments to sandbags and skids would be made, as necessary, to minimize pipeline stresses. After mining and allowing for a settlement period, the pipelines would be reburied within Texas Eastern's existing easements.

The general location of the project facilities is shown in appendix 1.[1]

Land Requirements for Construction

The project would disturb about 34.0 acres of land for the excavation, abandonment, replacement, elevation, and reburial at the CONSOL mine, most of which consists of existing previously disturbed easements. The acreages include permanent and temporary construction right-of-way, access roads, and wareyard. Following pipeline reburial and restoration, Texas Eastern would continue to maintain its existing 9.8 acres of easement at the CONSOL mine for the continued permanent operation of its pipelines; the remaining acreage would be restored and allowed to revert to former uses.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us [2] to discover and address concerns the public may have about proposals. This process is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. We will consider all filed comments during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the excavation, abandonment, replacement, temporary elevation, and reburial of Texas Eastern's existing pipeline facilities under these general headings:

- Geology and soils;
- land use;
- water resources, fisheries, and wetlands;
- cultural resources;
- vegetation and wildlife;
- air quality and noise;
- endangered and threatened species;
- public safety; and
- cumulative impacts.

We will also evaluate reasonable alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

The EA will present our independent analysis of the issues. The EA will be available in the public record through eLibrary. Depending on the comments received during the scoping process, we may also publish and distribute the EA to the public for an allotted comment period. We will consider all comments on the EA before making our recommendations to the Commission. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section beginning on page 5.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate with us in the preparation of the EA.[3] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with the Pennsylvania State Historic Preservation Office (SHPO), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.[4] We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPO as the project develops. On natural gas facility project, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for this project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please send your comments so that the Commission receives them in Washington, DC on or before December 17, 2014.

For your convenience, there are three methods which you can use to submit your comments to the Commission. In all instances please reference the appropriate project docket number (CP14–545–000) with your submission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov.*

(1) You can file your comments electronically using the *eComment* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* This is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You can file your comments electronically using the *eFiling* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''*eRegister.''* You must select the type of filing you are making. If you are filing a comment on a particular project, please select ''Comment on a Filing''; or

[1] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary'' or from the Commission's Public Reference Room, 888 First Street NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

[2] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

[3] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

[4] The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

(3) You can file a paper copy of your comments by mailing them to the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

If we publish and distribute the EA, copies will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 2).

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an ''intervenor'' which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are in the User's Guide under the ''e-filing'' link on the Commission's Web site.

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site at *www.ferc.gov* using the ''eLibrary'' link. Click on the eLibrary link, click on ''General Search'' and enter the docket number, excluding the last three digits in the Docket Number field (i.e., CP14–545). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission now offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Finally, public meetings or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–27611 Filed 11–20–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14628–000]

Minnesota Leased Housing Associates IV, Limited Partnership; Notice of Scoping Meeting, Initial Information Meeting, and Soliciting Scoping Comments for an Applicant Prepared Environmental Assessment Using the Alternative Licensing Process

a. Type of Filing: Notice of Intent to File License Application and Pre-Application Document for an Original License.

b. Project No.: 14628–000.

c. Applicant: Minnesota Leased Housing Associates IV, Limited Partnership (Minnesota Housing Associates).

d. Name of Project: A-Mill Artists Loft Hydroelectric Project (A-Mill Project).

e. Location: On the Mississippi River, in the city of Minneapolis, Hennepin County, Minnesota.

f. Filed Pursuant to: Federal Power Act, 16 U.S.C. 791(a)–825(r).

g. Applicant Contact: Owen Metz, 2905 Northwest Blvd., Suite 150, Plymouth, MN 55441; (763) 354–5618; email *ometz@dominiuminc.com.*

h. FERC Contact: Janet Hutzel at (202) 502–8675; or email at *janet.hutzel@ferc.gov.*

i. Deadline for filing scoping comments: January 3, 2015.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–14628–000.

j. The proposed project would consist of: (1) Removal of the existing concrete bulkhead blocking the existing intake structure and installation of a new trash rack at the intake; (2) an existing headrace tunnel that would be rehabilitated and sleeved with a new horizontal 600-foot-long, 5-foot-diameter steel penstock; (3) a new vertical 50-foot-long, 5-foot diameter steel pipe installed in an existing downstream drop-shaft; (4) a new sluice gate; (5) a new 650-kilowatt turbine/generator set and related control system; (6) a new outlet structure consisting of a 4-foot-high by 6-foot-wide concrete box culvert installed on the invert of the existing downstream tailrace; and (7) appurtenant facilities.

k. Scoping Process: Minnesota Housing Associates intends to utilize the Federal Energy Regulatory Commission's (Commission) alternative licensing process (ALP). Under the ALP, Minnesota Housing Associates will prepare an Applicant Prepared Environmental Assessment (APEA) and license application for the A-Mill Project.

Minnesota Housing Associates expects to file with the Commission, the APEA and the license application for the A-Mill Project by January 2015. Although the Commission's intent is to prepare an environmental assessment (EA), there is the possibility that an Environmental Impact Statement (EIS) will be required. Nevertheless, this meeting will satisfy the NEPA scoping requirements, irrespective of whether an EA or EIS is issued by the Commission.

The purpose of this notice is to inform you of the opportunity to participate in the upcoming scoping meetings and environmental site review identified

below, and to solicit your scoping comments.

Scoping Meetings, Initial Information Meeting (also known as a Joint Meeting), and Environmental Site Review [1]

Minnesota Housing Associates will hold two scoping meetings, one in the daytime and one in the evening, to help us identify the scope of issues to be addressed in the APEA. The initial information meeting will be held at the same time as the daytime scoping meeting.

The daytime scoping meeting will focus on resource agency concerns, while the evening scoping meeting is primarily for public input. All interested individuals, organizations, and agencies are invited to attend one or both of the meetings, and to assist the staff in identifying the environmental issues that should be analyzed in the APEA. The times and locations of these meetings and environmental site review are as follows:

Daytime Meeting

Thursday, December 4, 2014 at 12 p.m. (CST), 1000 LaSalle Avenue, Room 202 of the Terrence Murphy Hall, Minneapolis, MN 55403.

Evening Meeting

Thursday, December 4, 2014 at 5 p.m. (CST), 1000 LaSalle Avenue, Room 202 of the Terrence Murphy Hall, Minneapolis, MN 55403.

Environmental Site Review

Thursday, December 4, 2014 at 2 p.m. (CST), Xcel Energy Water Power Park, 206 Main Street SE., Minneapolis, MN 55414.

Please notify Neal Route at (763) 354–5500, or email: *nroute@dominiuminc.com* if you plan to attend the environmental site review.

To help focus discussions, Minnesota Housing Associates will mail the Scoping Document 1 (SD1), outlining the subject areas to be addressed in the APEA, to the parties on the mailing and distribution list. Copies of the SD1 also will be available at the scoping meetings. Minnesota Housing Associates will file SD1 with the Commission and the document will be available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits (P–14628) in the docket number field to access the document.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact *FERCOnlineSupport@ferc.gov.*

Based on all written comments received, a Scoping Document 2 (SD2) may be issued. SD2 will include a revised list of issues, based on the scoping sessions.

Meeting Objectives

At the scoping meetings, Minnesota Housing Associates will: (1) Summarize the environmental issues tentatively identified for analysis in the APEA; (2) solicit from the meeting participants all available information, especially quantifiable data, on the resources at issue; (3) encourage statements from experts and the public on issues that should be analyzed in the APEA, including viewpoints in opposition to, or in support of, Minnesota Housing Associates' preliminary views; (4) determine the resource issues to be addressed in the APEA; and (5) identify those issues that require a detailed analysis, as well as those issues that do not require a detailed analysis.

Meeting Procedures

The meetings will be recorded by a stenographer and will become part of the formal record of the Commission proceeding on the project.

Dated: November 14, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–27554 Filed 11–20–14; 8:45 am]

BILLING CODE 6717–01–P

[1] With this notice, 18 CFR 4.38(b)(3)(ii), the requirement to hold an initial information meeting, also known as a joint meeting, no earlier than 30 days and no later than 60 days after the Alternative Licensing Process is approved, is waived. Holding the initial information meeting outside the required timeframe will result in greater participation from the licensing participants.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP14–504–000]

Transcontinental Gas Pipe Line Company, LLC; Notice of Availability of the Environmental Assessment for the Proposed Rock Springs Expansion Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) for the Rock Springs Expansion Project (Project), proposed by Transcontinental Gas Pipe Line Company, LLC (Transco) in the above referenced docket. Transco requests authorization to construct and operate natural gas pipeline facilities in Lancaster County, Pennsylvania and Cecil County, Maryland. The Project would provide 192,000 dekatherms of natural gas per day to the Wildcat Point Generating Facility in Cecil County, Maryland.

The EA assesses the potential environmental effects of the construction and operation of the proposed Project in accordance with the requirements of the National Environmental Policy Act (NEPA). The FERC staff concludes that approval of the proposed Project, with appropriate mitigating measures, would not constitute a major federal action significantly affecting the quality of the human environment.

The Maryland Department of Natural Resources participated as a cooperating agency in the preparation of the EA. Cooperating agencies have jurisdiction by law or special expertise with respect to resources potentially affected by the proposal and participate in the National Environmental Policy Act analysis.

Transco proposes to: (1) Construct and operate a 11.2-mile-long pipeline lateral from Transco's Mainline Systems ''A'' and ''B'' in Lancaster County, Pennsylvania to the Old Dominion Electric Cooperative's Wildcat Point Generating Facility; (2) a new 4,000-horsepower electric compressor station at the terminus of the lateral, and appurtenant facilities; and (3) modify piping and valves at its existing Compressor Station 200 in Chester County, Pennsylvania.

The FERC staff mailed copies of the EA to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; potentially affected landowners and other interested individuals and groups; newspapers and libraries in the project area; and parties to this proceeding. In addition, the EA is available for public viewing on the FERC's Web site (*www.ferc.gov*) using the eLibrary link. A limited number of copies of the EA are available for distribution and public inspection at:

Federal Energy Regulatory Commission, Public Reference Room, 888 First Street NE., Room 2A, Washington, DC 20426, (202) 502–8371.

Any person wishing to comment on the EA may do so. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more

specific your comments, the more useful they will be. To ensure that the Commission has the opportunity to consider your comments prior to making its decision on this Project, it is important that we receive your comments in Washington, DC on or before December 15, 2014.

For your convenience, there are three methods in which you can use to file your comments to the Commission. In all instances, please reference the project docket numbers (CP14–504–000) with your submission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov*.

(1) You may file your comments electronically using the *eComment* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings*. This is an easy method for submitting brief, text-only comments on a project;

(2) You may also file your comments electronically using the *eFiling* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings*. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''*eRegister*.'' You must select the type of filing you are making. If you are filing a comment on a particular project, please select ''Comment on a Filing''; or

(3) You may file a paper copy of your comments by mailing them to the following address:

Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First St. NE., Room 1A, Washington, DC 20426.

Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214).[1] Only intervenors have the right to seek rehearing of the Commission's decision. The Commission grants affected landowners and others with environmental concerns intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which no other party can adequately represent. Simply filing environmental comments will not give you intervenor status, but you do not need intervenor status to have your comments considered.

[1] See the previous discussion on the methods for filing comments.

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search,'' and enter the docket number excluding the last three digits in the Docket Number field (i.e., CP14–504). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

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Dated: November 14, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–27552 Filed 11–20–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PF14–10–000]

Transcontinental Gas Pipe Line Company, LLC, Supplemental Notice of Intent to Prepare an Environmental Assessment for the Planned Dalton Expansion Project, Request for Comments on Environmental Issues

On October 21, 2014, the Commission issued the *Notice of Intent to Prepare an Environmental Assessment for the Planned Dalton Expansion Project, and Notice of Public Scoping Meeting* (NOI). It has come to our attention that the environmental mailing list was not provided copies of the NOI; therefore, we are issuing this Supplemental NOI to extend the scoping period and provide additional time for interested parties to file comments on environmental issues. The NOI identified November 20, 2014 as the close of the scoping period. Please note that the scoping period is now extended and will close on December 20, 2014.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of Transcontinental Gas Pipe Line Company, LLC's (Transco's) Dalton Expansion Project (Project) involving construction and operation of new pipeline and aboveground facilities in Georgia and the modification of Transco's existing mainline system in Maryland, Virginia, and North Carolina. The Commission will use this EA in its decision-making process to determine whether the Project is in the public convenience and necessity.

This notice is being sent to the Commission's current environmental mailing list for this Project. State and local government representatives should notify their constituents of this planned Project and encourage them to comment on their areas of concern.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the planned facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the Project, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

A fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' is available for viewing on the FERC Web site (*www.ferc.gov*). This fact sheet addresses a number of typically asked questions, including the use of eminent domain and how to participate in the Commission's proceedings.

Summary of the Planned Project

Transco plans to construct and operate about 110.8 miles of new natural gas pipeline in Coweta, Carroll, Douglas, Paulding, Bartow, Gordon, and Murray Counties, Georgia and a new compressor station in Carroll County, Georgia. In addition, Transco plans to modify facilities along its existing mainline system in Maryland, Virginia, and North Carolina to accommodate bidirectional flow. Transco has indicated that the Project would provide 448,000 dekatherms per day of incremental firm transportation service to markets in northwest Georgia.

The Project would include the installation of the following facilities:

- A new 21,830 horsepower compressor station (Compressor Station 116) in Carroll County, Georgia;
- three new meter stations in Bartow and Murray counties, Georgia;
- about 7.6 miles of new 30-inch-diameter pipeline in Coweta and Caroll Counties, Georgia;
- 48.2 miles of new 24-inch-diameter pipeline in Carroll, Douglas, Paulding, and Bartow Counties, Georgia;
- 53.5 miles of new 20-inch-diameter pipeline in Bartow, Gordon, and Murray Counties, Georgia;
- 1.5 miles of new 16-inch-diameter pipeline in Murray County, Georgia; and
- ancillary facilities associated with the new pipeline including mainline valves and pig [1] launchers/receivers facilities.

The Dalton Expansion Project would also include the following modifications to Transco's existing mainline facilities:

- Addition of 30-inch mainline regulators at a compressor station in Howard County, Maryland;
- addition of valves and yard piping for south flow compression at compressor stations in Pittsylvania and Prince William Counties, Virginia;
- modifications at a compressor station in Mecklenburg County, Virginia;
- modifications at meter stations in Rockingham, Warren, Northampton, and Buffalo Island Counties, North Carolina, and Pittsylvania, Halifax, Mecklenburg, Brunswick, and Greensville Counties, Virginia; and
- modifications at two mainline valves in Rockingham County, North Carolina.

The general location of the Project facilities is shown in appendix 1.[2]

Land Requirements for Construction

Construction of the planned pipeline and aboveground facilities in Georgia would disturb about 1,140 acres of land. Following construction, Transco would maintain about 685 acres for permanent operation of the Project's facilities; the remaining acreage would be restored and revert to former uses. About 66 percent of the planned pipeline route parallels existing pipeline, utility, or road rights-of-way. Modifications to Transco's mainline facilities in Maryland, Virginia, and North Carolina would occur within the boundaries of the existing facilities.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us [3] to discover and address concerns the public may have about proposals. This process is referred to as scoping. The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. We will consider all filed comments during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the Project under these general headings:

- Geology and soils;
- water resources, fisheries, and wetlands;
- vegetation and wildlife;
- endangered and threatened species;
- land use;
- socioeconomics;
- cultural resources;
- air quality and noise; and
- public safety.

We will also evaluate possible alternatives to the Project or portions of the Project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Although no formal application has been filed, we have already initiated our NEPA review under the Commission's pre-filing process. The purpose of the pre-filing process is to encourage early involvement of interested stakeholders and to identify and resolve issues before the FERC receives an application. As part of our pre-filing review, we have begun to contact some federal and state agencies to discuss their involvement in the scoping process and the preparation of the EA. With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues related to this Project to formally cooperate with us in the preparation of the EA [4]. Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

The EA will present our independent analysis of the issues. The EA will be available in the public record through eLibrary. Depending on the comments received during the scoping process, we may also publish and distribute the EA to the public for an allotted comment period. We will consider all comments on the EA before we make our recommendations to the Commission. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section beginning on page 6.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with the applicable State Historic Preservation Office(s), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the Project's potential effects on historic properties.[5] We will define the Project-specific Area of Potential Effects (APE) in consultation with the SHPO(s) as the Project develops. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for this Project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Currently Identified Environmental Issues

We have already identified several issues that we think deserve attention based on a preliminary review of the planned facilities and the environmental information provided by Transco and public comments. This preliminary list of issues may change based on your comments and our analysis.

- *Geology*—Effects as a result of blasting to remove existing surface and

[1] A ''pig'' is a tool that the pipeline company inserts into and pushes through the pipeline for cleaning the pipeline, conducting internal inspections, or other purposes.

[2] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary'' or from the Commission's Public Reference Room, 888 First Street NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

[3] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

[4] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

[5] The Advisory Council on Historic Preservation regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

subsurface bedrock during Project construction.

• *Biological Resources*—Effects on threatened and endangered species and sensitive habitats potentially occurring within or adjacent to the Project right-of-way.

• *Water Resources*—Effects on waterbodies and wetlands.

• *Land Use*—Effects on residential areas and agricultural lands during construction and operation of Project facilities.

• *Cultural Resources*—Effects on archaeological sites and historic resources.

• *Air Quality and Noise*—Effects on the local air quality and noise environment from construction and operation and maintenance of Project facilities.

Public Participation

You can make a difference by providing us with your specific comments or concerns about the Project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that your comments are timely and properly recorded, please send your comments so that the Commission receives them in Washington, DC on or before December 20, 2014.

For your convenience, there are three methods you can use to submit your comments to the Commission. In all instances, please reference the Project docket number (PF14–10–000) with your submission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov*.

(1) You can file your comments electronically using the *eComment* feature located on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings*. This is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You can file your comments electronically using the *eFiling* feature located on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings*. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''*eRegister*.'' You must select the type of filing you are making. If you are filing a comment on a particular project, please select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for Project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the Project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the planned Project.

Copies of the EA will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 2).

Becoming an Intervenor

Once Transco files its application with the Commission, you may want to become an ''intervenor'' which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are in the User's Guide under the ''e-filing'' link on the Commission's Web site. Please note that the Commission will not accept requests for intervenor status at this time. You must wait until the Commission receives a formal application for the Project.

Additional Information

Additional information about the Project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number, excluding the last three digits in the Docket Number field (i.e., PF14–10). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

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Finally, public meetings or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: November 14, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–27548 Filed 11–20–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13563–003]

Juneau Hydropower, Inc.; Notice of Intent To Prepare Environmental Impact Statement and Soliciting Comments, and Final Recommendations, Terms and Conditions, and Prescriptions

November 17, 2014.

Take notice that the following hydroelectric application and applicant-prepared environmental assessment has been filed with Commission and is available for public inspection.

a. *Type of Application:* Original Major License.

b. *Project No.:* 13563–003.

c. *Date filed:* May 29, 2014.

d. *Applicant:* Juneau Hydropower, Inc.

e. *Name of Project:* Sweetheart Lake Hydroelectric Project.

f. *Location:* On Lower Sweetheart Lake and Sweetheart Creek in the City and Borough of Juneau, Alaska. The project would occupy about 2,058 acres of federal lands located in the Tongass

National Forest administered by the U.S. Forest Service.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Duff W. Mitchell, Business Manager, Juneau Hydropower, Inc., P.O. Box 22775, Juneau, AK 99802; (907) 789–2775.

i. *FERC Contact:* John Matkowski at (202) 502–8576, *john.matkowski@ferc.gov.*

j. Deadline for filing comments, final recommendations, terms and conditions, and prescriptions: 60 days from the issuance date of this notice; reply comments are due 105 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file comments, and final recommendations, terms and conditions, and prescriptions using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–13563–003.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted for filing and is now ready for environmental analysis.

l. The Commission intends to prepare an Environmental Impact Statement (EIS) on the project in accordance with the National Environmental Policy Act. The EIS will consider both site-specific and cumulative environmental impacts and reasonable alternatives to the proposed action.

m. The proposed Sweetheart Lake Project would consist of the following new features: (1) A 280-foot-long, 111-foot-high roller compacted concrete gravity dam with a 125-foot-long spillway located at the outlet of Sweetheart Lake; (2) a 128,019 acre-foot impoundment at normal-maximum water level; (3) a 525-foot-long, 10-foot-high, 10-foot-wide arched reservoir outlet tunnel at the right dam abutment; (4) a 45-foot-long, 25-foot-wide, 16-foot-high rectangular concrete intake structure with six 7-foot-diameter, 10-foot-high cylindrical fish screens adjacent to the right dam abutment; (5) a 9,621-foot-long, 15-foot-wide,15-foot-high arched, unlined power tunnel; (6) a 9-foot-diameter, 896-foot-long saddle-supported steel penstock installed within the lower power tunnel; (7) three, 3- to 7-foot-diameter, approximately 160-foot-long buried steel penstocks connecting the lower portion of the power tunnel to the powerhouse; (8) a 160-foot-long, 60-foot-wide, 30-foot-high powerhouse; (9) three 6.6-megawatt (MW) horizontal-axis Francis turbine/generator units having a total capacity of 19.8 MW; (10) a 541-foot-long, 30- to 90-foot-wide tailrace discharging into Sweetheart Creek; (11) a 4,400-foot-long coastal access road; (12) a dock/landing site for aerial and marine vehicle access located on the east shore of Gilbert Bay; (13) a 45,900-foot-long, 138-kilovolt (kV) transmission line traversing Gilbert Bay, the Snettisham Peninsula, and Port Snettisham, consisting of: (a) Two buried segments totaling 4,800 feet in length, (b) two submarine segments totaling 25,700 feet in length, and (c) one 15,400-foot-long overhead segment; (14) a 14,800-foot-long, 12.47-kV service transmission line and communication cable providing electricity and communications to Sweetheart Dam; (15) an approximately 22,000-square-foot fenced switchyard; (16) a 25-foot-long, 5-foot-wide, 4-foot-deep smolt reentry pool adjacent to the powerhouse; (17) a 4,225-square-foot caretaker facility; (18) a 400-square-foot dam site shelter facility; and (19) appurtenant facilities. The project is estimated to generate an average of 116 gigawatt-hours annually.

n. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

All filings must (1) bear in all capital letters the title ''COMMENTS'', ''REPLY COMMENTS'', ''RECOMMENDATIONS,'' ''TERMS AND CONDITIONS,'' or ''PRESCRIPTIONS;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person submitting the filing; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. Each filing must be accompanied by proof of service on all persons listed on the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b), and 385.2010.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

o. Public notice of the filing of the initial development application, which has already been given, established the due date for filing competing applications or notices of intent. Under the Commission's regulations, any competing development application must be filed in response to and in compliance with public notice of the initial development application. No competing applications or notices of intent may be filed in response to this notice.

p. Procedural Schedule:

The application will be processed according to the following hydro licensing schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Filing of final recommendations, terms and conditions, and prescriptions.	January 2015.
Commission issues Draft EIS	August 2015.
Comments on Draft EIS	October 2015.
Commission Issues Final EIS	March 2016.

q. A license applicant must file no later than 60 days following the date of issuance of this notice: (1) A copy of the water quality certification; (2) a copy of the request for certification, including proof of the date on which the certifying agency received the request; or (3) evidence of waiver of water quality certification.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–27612 Filed 11–20–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL14–95–001]

PJM Interconnection, L.L.C.; Notice of Filing

Take notice that on November 13, 2014, pursuant to section 206 of the Federal Power Act, 16 USC 824(e) and Part 35 of the Federal Energy Regulatory Commission's (Commission) Regulations, 18 CFR part 35, PJM Interconnection, L.L.C. filed clarifications to the language originally proposed on August 26, 2014, in compliance with the October 31, 2014 Order of the Federal Energy Regulatory Commission.[1]

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on December 4, 2014.

[1] *PJM Interconnection, L.L.C.,* 149 FERC ¶ 61,091 (2014) (October 31, 2014 Order).

Dated: November 14, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–27547 Filed 11–20–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL15–19–000]

Avista Corporation; Notice of Petition for Declaratory Order

Take notice that on November 10, 2014, pursuant to Rule 207 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207, and sections 366.3(b)(i) and 366.3(d) of the Commission's regulations, Avista Coproration (Avista) requesting exemption from certain requirements under the Public Utility Holding Company Act of 2005 (PUHCA 2005),[1] as more fully described in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern time on December 10, 2014.

[1] 42 U.S.C. 16451, et seq. (PUHCA 2005). *See* 42 U.S.C. 16454 (providing for certain exemptions from the requirements of PUHCA 2005).

Dated: November 14, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–27550 Filed 11–20–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15–12–000]

Columbia Gas Transmission, LLC; Notice of Request Under Blanket Authorization

Take notice that on November 4. 2014, Columbia Gas Transmission (Columbia), 5151 San Felipe, Suite 2500, Houston, Texas 77056, filed in the above Docket, a prior notice request pursuant to sections 157.205 and 157.208 of the Commission's regulations under the Natural Gas Act (NGA), and Columbia's authorization in Docket No. CP83–76–000 for authorization to abandon and construct certain facilities referred to collectively as the Broad Run Connector Project (Project), all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or TTY, contact (202) 502–8659.

Any questions concerning this application may be directed Fredric J. George, Senior Counsel, Columbia Gas Transmission, LLC, P.O. Box 1273, Charleston, West Virginia 25325–1273, at (304) 357–2359.

Specifically, Columbia proposes to abandon by removal an existing natural gas-fired 3,000 horsepower (HP) reciprocating engine, and to construct an 8,000 HP electric motor driven compressor and appurtenant facilities. The proposed increase in capacity will enable Columbia to provide its customer up to 582,000 dekatherms of gas transportation per day. Columbia and its customer have agreed to a negotiated rate for the service to be rendered as a result of this expansion and have executed a Precedent Agreement

confirming their agreement. Columbia proposes a rolled-in rate treatment for the Project. The estimated cost of the project is $29.7 million.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Any person may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention. Any person filing to intervene or the Commission's staff may, pursuant to section 157.205 of the Commission's Regulations under the Natural Gas Act (NGA) (18 CFR 157.205) file a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*www.ferc.gov*) under the ''e-Filing'' link.

Dated: November 14, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–27546 Filed 11–20–14; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15–11–000]

Columbia Gas Transmission, LLC; Notice of Request Under Blanket Authorization

Take notice that on November 4, 2014, Columbia Gas Transmission, LLC (Columbia), 5151 San Felipe, Suite 2500, Houston, Texas 77056 filed a prior notice request pursuant to sections 157.205 and 157.213 of the Commission's regulations under the Natural Gas Act for authorization to replace certain natural gas facilities located in York and Adams Counties, Pennsylvania. Specifically, Columbia proposes to replace 5.4 miles of 8-inch diameter bare steel pipe of Line 1655 with 6.5 miles of new 10-inch diameter coated steel pipeline. Columbia's proposed modifications will increase capacity on the terminus of Line 1655 from 38,290 dekatherms (Dth) per day to 50,290 Dth per day. The replacement is required due to the age and condition of the pipe, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may also be viewed on the web at *http://www.ferc.gov* using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TTY, (202) 502–8659.

Any questions regarding this Application should be directed to William A. Sala, Jr., Counsel, Columbia Gas Transmission, LLC, 5151 San Felipe, Suite 2500, Houston, Texas, or by calling (713) 386–3743.

Any person may, within 60 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention. Any person filing to intervene or the Commission's staff may, pursuant to section 157.205 of the Commission's Regulations under the NGA (18 CFR 157.205) file a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenter's will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenter's will not be required to serve copies of filed documents on all other parties. However, the non-party commentary, will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests, and interventions via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*www.ferc.gov*) under the ''e-Filing'' link. Persons unable to file electronically should submit original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Dated: November 14, 2014.

Kimberly D. Bose,

Secretary.

[FR Doc. 2014–27553 Filed 11–20–14; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–RCRA–2014–0296; FRL–9919–01–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; 2015 Hazardous Waste Report, Notification of Regulated Waste Activity, and Part A Hazardous Waste Permit Application and Modification (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), 2015 Hazardous Waste Report, Notification of Regulated Waste Activity, and Part A Hazardous Waste Permit Application and Modification (Renewal) (EPA ICR No. 0976.17, OMB Control No. 2050–0024) 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 December 31, 2014. Public comments were previously requested via the **Federal Register** (79 FR 34733) on June 18, 2014 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 December 22, 2014.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–RCRA–2014–0296, to (1) EPA online using *www.regulations.gov* (our preferred method), by email to *rcra-docket@epa.gov,* 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: Peggy Vyas, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 703–308–5477; fax number: 703–308–8433; email address: *vyas.peggy@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, EPA 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: Section 3002 of RCRA requires hazardous waste generators to report, at least every 2 years, the quantity and nature of hazardous waste generated and managed each year. Section 3004 requires treatment, storage, and disposal facilities (TSDFs) to report any waste received. This is mandatory reporting. The information is collected via the Hazardous Waste Report (EPA Form 8700–13 A/B). This form is also known as the ''Biennial Report'' form.

Section 3010 of RCRA requires any person who generates or transports regulated waste or who owns or operates a facility for the treatment, storage, or disposal of regulated waste to notify the EPA of their activities, including the location and general description of activities and the regulated wastes handled. The entity is then issued an EPA Identification number. Entities use the Notification Form (EPA Form 8700–12) to notify EPA of their hazardous waste activities. This form is also known as the ''Notification'' form.

Section 3005 of RCRA requires TSDFs to obtain a permit. To obtain the permit, the TSDF must submit an application describing the facility's operation. The RCRA Hazardous Waste Part A Permit Application form (EPA Form 8700–23) defines the processes to be used for treatment, storage, and disposal of hazardous wastes; the design capacity of such processes; and the specific hazardous wastes to be handled at the facility. This form is also known as the ''Part A'' form.

Form Numbers: 8700–12, 8700–13A/B, and 8700–23.

Respondents/affected entities: Business or other for-profit, State, Local, or Tribal governments.

Respondent's obligation to respond: Mandatory (RCRA Sections 3002, 3304, 3005, 3010).

Estimated number of respondents: 57,879.

Frequency of response: Biennially.

Total estimated burden: 619,489 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $25,530,368 (per year), includes $285,329 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is increase of 186,586 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is due to an increase in the number of projected respondents to the 2015 Hazardous Waste Report vs the 2013 Hazardous Waste Report.

Courtney Kerwin,

Acting Director, Collection Strategies Division.

[FR Doc. 2014–27533 Filed 11–20–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2014–0350, FRL 9915–93–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; National Listing of Fish Advisories (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), National Listing of Fish Advisories, (EPA ICR Number 1959.05, OMB Control Number 2040–0226) 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 November 30, 2014. Public comments were previously requested via the **Federal Register** (79 FR 33188) on June 10, 2014 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 must be submitted on or before December 22, 2014.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OW–2014–0350, to (1) EPA online using *www.regulations.gov* (our preferred method), by email to *OW-Docket@epa.gov,* 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: LCDR Samantha Fontenelle, Office of Science and Technology, Standards and Health Protection Division, MC–4305T, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 566–2083; fax number: (202) 566–0409; email address: *fontenelle.samantha@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: The National Listing of Fish Advisories (NLFA) database contains information on the number of advisories issued by each state, territory, or tribe annually. The advisory information collected identifies the waterbody under advisory, the fish or shellfish species and size ranges included in the advisory, the chemical contaminants and residue levels causing the advisory to be issued, the waterbody type (river, lake, estuary, coastal waters), and the target populations to whom the advisory is directed. This information is collected under the authority of section 104 of the Clean Water Act, which provides for the collection of information to be used to protect human health and the environment. The results of the survey are shared with states, territories, tribes, other federal agencies, and the general public through the NLFA database and the distribution of biennial fish advisory fact sheets. The responses to the survey are voluntary and the information requested is part of the state public record associated with the advisories. No confidential business information is requested.

Form Numbers: None.

Respondents/Affected entities: Entities potentially affected by this action are Administrators of Public Health and Environmental Quality Programs in state and tribal governments.

Respondent's obligation to respond: Voluntary (Clean Water Act, Section 104).

Estimated number of respondents: 92 total.

Frequency of response: Annual.

Total estimated burden: 1,884 labor hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $73,116 (per year), which includes $607 annualized operation & maintenance costs. No capital or startup costs are required.

Changes in Estimates: There is a decrease of 1,452 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This decrease is due to a change in program requirements (i.e., the elimination of the State Fish Advisory Program Questionnaire).

Courtney Kerwin,

Acting Director, Collection Strategies Division.

[FR Doc. 2014–27534 Filed 11–20–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9919–61–OAR]

California State Nonroad Engine Pollution Control Standards; Portable Diesel-Fueled Engines Air Toxics Control Measure; Request for Confirmation That Amendments Are Within the Scope of Previous Authorization; Opportunity for Public Hearing and Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The California Air Resources Board (CARB) has notified the Environmental Protection Agency (EPA) that it adopted amendments to California's Portable Diesel-Fueled Engines Air Toxics Control Measure (Portable Engine ATCM) in 2007, 2009, and 2010. By letter dated September 15, 2014, CARB asked that EPA authorize these amendments pursuant to the Clean Air Act (CAA or Act). CARB requested EPA's confirmation that the amendments are within the scope of a prior authorization, or, in the alternative, that the amendments merit full authorization. This notice announces that EPA has tentatively scheduled a public hearing to consider California's request, and that EPA is now accepting written comment on the request.

DATES: EPA has tentatively scheduled a public hearing concerning CARB's request on January 14, 2015 at 10 a.m. ET. EPA will hold a hearing only if any party notifies EPA by December 15, 2014 to express interest in presenting the Agency with oral testimony. Parties that wish to present oral testimony at the public hearing should provide written notice to David Read at the email address noted below. If EPA receives a request for a public hearing, that hearing will be held at the William Jefferson Clinton Building (North), Room 5530 at 1200 Pennsylvania Ave. NW., Washington, DC 20460. If EPA does not receive a request for a public hearing, then EPA will not hold a hearing, and will instead consider CARB's request based on written submissions to the docket. Any party may submit written comments until February 16, 2015.

Any person who wishes to know whether a hearing will be held may call David Read at (734) 214–4367 on or after December 17, 2014.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2014–0798, by one of the following methods:

- Online at *http://www.regulations.gov:* Follow the Online Instructions for Submitting Comments.
- Email: *a-and-r-docket@epa.gov.*
- Fax: (202) 566–9744.
- Mail: Air and Radiation Docket, Docket ID No. EPA–HQ–OAR–2014–0798, U.S. Environmental Protection Agency, Mail code: 6102T, 1200 Pennsylvania Avenue NW., Washington, DC 20460. Please include a total of two copies.
- Hand Delivery: EPA Docket Center, Public Reading Room, EPA West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Online Instructions for Submitting Comments: Direct your comments to

Docket ID No. EPA–HQ–OAR–2014–0798. EPA's policy is that all comments we receive will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov*, your email address will automatically be captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

EPA will make available for public inspection materials submitted by CARB, written comments received from any interested parties, and any testimony given at the public hearing. Materials relevant to this proceeding are contained in the Air and Radiation Docket and Information Center, maintained in Docket ID No. EPA–HQ–OAR–2014–0798. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the Air and Radiation Docket in the EPA Headquarters Library, EPA West Building, Room 3334, located at 1301 Constitution Avenue NW., Washington, DC. The Public Reading Room is open to the public on all federal government work days from 8:30 a.m. to 4:30 p.m.; generally, it is open Monday through Friday, excluding holidays. The telephone number for the Reading Room is (202) 566–1744. The Air and Radiation Docket and Information Center's Web site is *http://www.epa.gov/oar/docket.html.* The electronic mail (email) address for the Air and Radiation Docket is: *a-and-r-Docket@epa.gov*, the telephone number is (202) 566–1742, and the fax number is (202) 566–9744. An electronic version of the public docket is available through the federal government's electronic public docket and comment system. You may access EPA dockets at *http://www.regulations.gov.* After opening the *http://www.regulations.gov* Web site, enter, in the ''Enter Keyword or ID'' fill-in box to view documents in the record. Although a part of the official docket, the public docket does not include Confidential Business Information (''CBI'') or other information whose disclosure is restricted by statute.

EPA's Office of Transportation and Air Quality also maintains a Web page that contains general information on its review of California waiver and authorization requests. Included on that page are links to prior waiver and authorization **Federal Register** notices. The page can be accessed at *http://www.epa.gov/otaq/cafr.htm.*

FOR FURTHER INFORMATION CONTACT: David Read, Attorney, Office of Transportation and Air Quality, U.S. Environmental Protection Agency, 2565 Plymouth Road, Ann Arbor, MI 48105. Telephone: (734) 214–4367. Fax: (734) 214–4212. Email: *read.david@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. California's Portable Engine ATCM Regulations

California initially adopted its Portable Engine ATCM regulations on February 26, 2004 as part of a broad California program to reduce emissions of diesel particulate matter. The Portable Engine ATCM regulations applied to in-use, portable, off-road [1] diesel-fueled engines rated 50 brake horsepower (bhp) and greater. These engines were required to be certified to certain emission standards by January 1, 2010, unless the engines were designated as low-use engines or as engines exclusively used in emergency applications. The initial Portable Engine ATCM became operative under state law on March 11, 2005 [2] and EPA authorized the regulations on November 29, 2012.[3]

As authorized, the Portable Engine ATCM regulations require subject engines to meet specified emission standards, and require fleets of in-use diesel-fueled portable engines to meet fleet-average standards for diesel PM emissions that become increasingly more stringent in 2013, 2017, and 2020.

II. The 2007 Amendments

CARB adopted the 2007 amendments at issue in this notice on July 31, 2007, and they became effective on September 12, 2007. The 2007 amendments were designed to extend temporary, emergency provisions CARB had adopted to address the inability of owners and operators to permit or register older engines that did not satisfy the Portable Engine ATCM certification requirement to meet the most stringent Federal or California emission standards. The 2007 amendments addressed this issue by (i) granting discretion to local air districts to permit or register uncertified portable engines that were operated in California within a designated time period prior to October 1, 2006, or that were low-use engines or used exclusively in emergency applications, (ii) allowing Tier 1 and Tier 2 engines that were in operation within a designated time period prior to October 1, 2006, but did not meet the most stringent emission requirements, to be permitted or registered until December 31, 2009, and (iii) and otherwise providing additional compliance flexibility.

III. The 2009 Amendments

In 2008, CARB adopted an In-Use Off-Road regulation [4] and a Truck and Bus regulation.[5] CARB then amended the Portable Engine ATCM to exempt certain engines (namely, secondary engines on two-engine cranes and two-engine sweepers, and on lattice boom cranes) that instead became subject to these other new regulations. CARB formally adopted the amendments to the Portable Engine ATCM on October 19, 2009 (the 2009 amendments).

IV. The 2010 Amendments

California formally approved the 2010 amendments to the Portable Engine ATCM on October 19, 2010 and January 20, 2011. The 2010 amendments became operative under State law on February 19, 2011. The 2010 amendments primarily provide additional exemptions (namely for snow removal vehicles and auxiliary engines on water well drilling rigs) and compliance flexibility for certain owners and operators of portable engines, as well as clarification or correction of perceived oversights in the law.

[1] The federal term ''nonroad'' and the California term ''off-road'' may be used interchangeably herein.

[2] The Portable Engine ATCM is set forth at 17 CCR 93116 et seq.

[3] 77 FR 72846 (December 6, 2012).

[4] The California In-Use Off-Road regulation is set forth at 13 CCR 2449 *et seq.*

[5] The California Truck and Bus regulation is set forth at 13 CCR 2025 *et seq.*

By letter dated September 15, 2014, CARB submitted a request to EPA pursuant to section 209(e) of the CAA for confirmation that the 2007, 2009, and 2010 amendments fall within the scope of EPA's previous authorization, or, in the alternative, that EPA grant a full authorization for those amendments.

V. Clean Air Act Nonroad Engine and Vehicle Authorizations

Section 209(e)(1) of the CAA prohibits States and local governments from adopting or attempting to enforce any standard or requirement relating to the control of emissions from new nonroad vehicles or engines. The Act also preempts States from adopting and enforcing standards and other requirements related to the control of emissions from non-new nonroad engines or vehicles. Section 209(e)(2), however, requires the Administrator, after notice and opportunity for public hearing, to authorize California to adopt and enforce standards and other requirements related to the control of emissions from non-new nonroad engines or vehicles. Section 209(e)(2), however, requires the Administrator, after notice and opportunity for public hearing, to authorize California to adopt and enforce standards and other requirements relating to the control of emissions from such vehicles or engines if California determines that California standards will be, in the aggregate, at least as protective of public health and welfare as applicable Federal standards. However, EPA shall not grant such authorization if it finds that (1) the determination of California is arbitrary and capricious; (2) California does not need such California standards to meet compelling and extraordinary conditions; or (3) California standards and accompanying enforcement procedures are not consistent with CAA section 209.[6] In addition, other states with air quality attainment plans may adopt and enforce such regulations if the standards and the implementation and enforcement procedures are identical to California's standards. On July 20, 1994, EPA promulgated a rule that sets forth, among other things, regulations providing the criteria, as found in section 209(e)(2), which EPA must consider before granting any California authorization request for new nonroad engine or vehicle emission standards.[7] EPA revised these regulations in 1997.[8] As stated in the preamble to the 1994 rule, EPA has historically interpreted the section 209(e)(2)(iii) ''consistency'' inquiry to require, at minimum, that California standards and enforcement procedures be consistent with section 209(a), section 209(e)(1), and section 209(b)(1)(C) (as EPA has interpreted that subsection in the context of section 209(b) motor vehicle waivers).[9]

In order to be consistent with section 209(a), California's nonroad standards and enforcement procedures must not apply to new motor vehicles or new motor vehicle engines. To be consistent with section 209(e)(1), California's nonroad standards and enforcement procedures must not attempt to regulate engine categories that are permanently preempted from state regulation. To determine consistency with section 209(b)(1)(C), EPA typically reviews nonroad authorization requests under the same ''consistency'' criteria that are applied to motor vehicle waiver requests. Pursuant to section 209(b)(1)(C), the Administrator shall not grant California a motor vehicle waiver if she finds that California ''standards and accompanying enforcement procedures are not consistent with section 202(a)'' of the Act. Previous decisions granting waivers and authorizations have noted that state standards and enforcement procedures are inconsistent with section 202(a) if: (1) There is inadequate lead time to permit the development of the necessary technology giving appropriate consideration to the cost of compliance within that time, or (2) the Federal and State testing procedures impose inconsistent certification requirements.[10]

If California amends regulations that EPA has already authorized, California can seek EPA confirmation that the amendments are within the scope of the previous authorization. A within-the-scope confirmation, without a full authorization review, is permissible if three conditions are met.[11] First, the amended regulations must not undermine California's determination that its standards, in the aggregate, are as protective of public health and welfare as applicable Federal standards. Second, the amended regulations must not affect consistency with section 202(a) of the Act. Third, the amended regulations must not raise any ''new issues'' affecting EPA's prior authorizations.

VI. EPA's Request for Comments

As stated above, EPA is offering the opportunity for a public hearing, and is requesting written comment on issues relevant to a within-the-scope analysis. Specifically, we request comment on whether California's 2007, 2009, or 2010 Portable Engine ATCM amendments: (1) Undermine California's previous determination that its standards, in the aggregate, are at least as protective of public health and welfare as comparable Federal standards; (2) affect the consistency of California's requirements with section 209 of the Act; or (3) raise any other new issues affecting EPA's previous authorization determinations.

Should any party believe that the amendments are not within the scope of the previous authorization, EPA also requests comment on whether the 2007, 2009, or 2010 Portable Engine ATCM amendments meet the criteria for a full authorization. Specifically, we request comment on: (a) Whether CARB's determination that its standards, in the aggregate, are at least as protective of public health and welfare as applicable Federal standards is arbitrary and capricious; (b) whether California needs such standards to meet compelling and extraordinary conditions; and (c) whether California's standards and

[6] EPA's review of California regulations under section 209 is not a broad review of the reasonableness of the regulations or its compatibility with all other laws. Sections 209(b) and 209(e) of the Clean Air Act limit EPA's authority to deny California requests for waivers and authorizations to the three criteria listed therein. As a result, EPA has consistently refrained from denying California's requests for waivers and authorizations based on any other criteria. In instances where the U.S. Court of Appeals has reviewed EPA decisions declining to deny waiver requests based on criteria not found in section 209(b), the Court has upheld and agreed with EPA's determination. *See Motor and Equipment Manufacturers Ass'n* v. *Nichols,* 142 F.3d 449, 462–63, 466–67 (D.C. Cir.1998), *Motor and Equipment Manufacturers Ass'n* v. *EPA,* 627 F.2d 1095, 1111, 1114–20 (D.C. Cir. 1979). *See also* 78 FR 58090, 58120 (September 20, 2013).

[7] 59 FR 36969 (July 20, 1994).

[8] 62 FR 67733 (December 30, 1997). The applicable regulations, now in 40 CFR part 1074, subpart B, § 1074.105, provide:

(a) The Administrator will grant the authorization if California determines that its standards will be, in the aggregate, at least as protective of public health and welfare as otherwise applicable Federal standards.

(b) The authorization will not be granted if the Administrator finds that any of the following are true:

(1) California's determination is arbitrary and capricious.

(2) California does not need such standards to meet compelling and extraordinary conditions.

(3) The California standards and accompanying enforcement procedures are not consistent with section 209 of the Act.

(c) In considering any request to authorize California to adopt or enforce standards or other requirements relating to the control of emissions from new nonroad spark-ignition engines smaller than 50 horsepower, the Administrator will give appropriate consideration to safety factors (including the potential increased risk of burn or fire) associated with compliance with the California standard.

[9] 59 FR 36969 (July 20, 1994).

[10] *Id; see also* 78 FR 58090, 58092 (September 20, 2013).

[11] *See* 78 FR 38970, 38972 (June 28, 2013).

accompanying enforcement procedures are consistent with section 209 of the Act.

VII. Procedures for Public Participation

If a hearing is held, the Agency will make a verbatim record of the proceedings. Interested parties may arrange with the reporter at the hearing to obtain a copy of the transcript at their own expense. Regardless of whether a public hearing is held, EPA will keep the record open until February 16, 2015. Upon expiration of the comment period, the Administrator will render a decision on CARB's request based on the record from the public hearing, if any, all relevant written submissions, and other information that she deems pertinent. All information will be available for inspection at the EPA Air Docket No. EPA–HQ–OAR–2014–0798.

Persons with comments containing proprietary information must distinguish such information from other comments to the greatest extent possible and label it as ''Confidential Business Information'' (''CBI''). If a person making comments wants EPA to base its decision on a submission labeled as CBI, then a non-confidential version of the document that summarizes the key data or information should be submitted to the public docket. To ensure that proprietary information is not inadvertently placed in the public docket, submissions containing such information should be sent directly to the contact person listed above and not to the public docket. Information covered by a claim of confidentiality will be disclosed by EPA only to the extent allowed, and according to the procedures set forth in 40 CFR part 2. If no claim of confidentiality accompanies the submission when EPA receives it, EPA will make it available to the public without further notice to the person making comments.

Dated: November 12, 2014.

Christopher Grundler,

Director, Office of Transportation and Air Quality, Office of Air and Radiation.

[FR Doc. 2014–27645 Filed 11–20–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9919–56–OAR]

California State Nonroad Engine Pollution Control Standards; Small Off-Road Engines Regulations; Tier 4 Off-Road Compression-Ignition Regulations; Exhaust Emission Certification Test Fuel for Off-Road Spark-Ignition Engines, Equipment, and Vehicles Regulations; Request for Within-the-Scope and Full Authorization; Opportunity for Public Hearing and Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The California Air Resources Board (CARB) has notified the Environmental Protection Agency (EPA) that it has adopted amendments to its spark-ignited (SI) Small Off-Road Engines (SORE) regulations (2011 SORE amendments), Tier 4 Off-Road Compression-Ignition (CI) regulations (2011 Tier 4 amendments), and Exhaust Emission Certification Test Fuel for Off-Road Spark-Ignition Engines, Equipment, and Vehicles regulations (2011 Certification Test Fuel amendments). By letter dated June 13, 2014, CARB asked that EPA authorize these amendments pursuant to section 209(e) of the Clean Air Act (CAA or Act) 42 U.S.C. 7543(e). CARB seeks confirmation that the amendments are within the scope of prior authorizations issued by EPA, or, in the alternative, that the amendments merit full authorization. This notice announces that EPA has tentatively scheduled a public hearing to consider California's authorization request for the 2011 SORE amendments, 2011 Tier 4 amendments, and 2011 Certification Test Fuel amendments, and that EPA is now accepting written comment on the request.

DATES: EPA has tentatively scheduled a public hearing concerning CARB's request on January 14, 2015, at 10 a.m. ET. EPA will hold a hearing only if any party notifies EPA by December 15, 2014 to express interest in presenting the Agency with oral testimony. Parties wishing to present oral testimony at the public hearing should provide written notice to Brenton Williams at the email address noted below. If EPA receives a request for a public hearing, that hearing will be held at the William Jefferson Clinton Building (North), Room 5530 at 1200 Pennsylvania Ave. NW., Washington, DC 20460. If EPA does not receive a request for a public hearing, then EPA will not hold a hearing, and instead will consider CARB's request based on written submissions to the docket. Any party may submit written comments until February 16, 2015.

Any person who wishes to know whether a hearing will be held may call Brenton Williams at (734) 214–4341 on or after December 17, 2014.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2014–0535, by one of the following methods:

- Online at *http://www.regulations.gov:* Follow the Online Instructions for Submitting Comments.
- Email: *a-and-r-docket@epa.gov.*
- Fax: (202) 566–9744.
- Mail: Air and Radiation Docket, Docket ID No. EPA–HQ–OAR–2014–0535, U.S. Environmental Protection Agency, Mail code: 6102T, 1200 Pennsylvania Avenue NW., Washington, DC 20460. Please include a total of two copies.
- Hand Delivery: EPA Docket Center, Public Reading Room, EPA West Building, Room 3334, 1301 Constitution Avenue NW., Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Online Instructions for Submitting Comments: Direct your comments to Docket ID No. EPA–HQ–OAR–2014–0535. EPA's policy is that all comments we receive will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or email. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *http://www.regulations.gov,* your email address will automatically be captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA

cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

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FOR FURTHER INFORMATION CONTACT: Brenton Williams, Attorney-Advisor, Compliance Division, Office of Transportation and Air Quality, U.S. Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105. Telephone: (734) 214–4341. Fax: (734) 214–4053. Email: *williams.brent@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. California's SORE Regulations

Small off-road engines and equipment [1] are rated at or below 19 kilowatts (kW) (25 horsepower (hp)). The vast majority of engines covered by the SORE regulations are SI engines that are used to power a broad range of equipment, including lawn mowers, leaf blowers, generators, and small industrial equipment. Exhaust and evaporative emissions from these engines are a significant source of hydrocarbons and oxides of nitrogen, pollutants that contribute to smog problems in California.

CARB promulgated its first SORE regulations in 1992 and amended them in 1993. EPA authorized the regulations, as amended, on July 5, 1995.[2] CARB further amended these regulations in 1994, 1995, and 1996, and EPA confirmed all the amendments to be within the scope of the prior approval on November 9, 2000.[3] CARB again amended the SORE regulations in 1998, this time requesting within-the-scope determination for all but one of the amendments, for which full authorization was requested. EPA issued its within-the-scope determination on November 9, 2000, for these former amendments, and a full authorization on November 10, 2003, for the latter amendment.[4] In 2000 and again in 2004, CARB amended the SORE regulations to more closely align with the federal SORE program. EPA confirmed that the 2000 amendments were within the scope of the previously granted SORE authorization in February, 2010, and also granted a full authorization for the 2004 amendments to standards and test procedures for certain nonroad compression ignition engines.[5] EPA issued a full authorization for CARB's 2004 amendments to the SI SORE regulations on December 11, 2006.[6]

CARB adopted additional SORE amendments on November 21, 2008.[7] and requested EPA authorization review. EPA provided opportunity for comment on that request [8] and is preparing a notice of final decision. The 2008 SORE amendments modified the emission credits program to provide manufacturers with additional flexibility. Additionally, manufacturers were permitted to use a certification fuel with up to ten volume percent ethanol content, provided that the same fuel is used for certification with the EPA.

CARB approved the 2011 SORE amendments at issue in this notice on December 16, 2011, and adopted them on October 25, 2012.[9] The 2011 SORE amendments became operative on January 10, 2013.[10] The 2011 SORE amendments modify California's existing SORE test procedures by aligning California procedures to be consistent with recent amendments by EPA to the federal certification and exhaust emission testing requirements at title 40, Code of Federal Regulations (CFR), Parts 1054 and 1065.[11] Part 1054 contains certification protocols, production-line testing requirements, credit-generation allowances, and other related provisions applicable to federally certified engines. Since CARB had previously promulgated California-specific versions of these provisions for SORE engines, the 2011 SORE amendments adopted Part 1054, but with modifications that substitute California's specific emission standards, production-line testing requirements and credit-allowances for the corresponding federal provisions.[12] Part 1065 specifies the ''state-of-the-art'' testing equipment, systems, and processes that must be utilized in conducting emissions testing of applicable engines. The 2011 SORE amendments align California test procedures for 2013 and later model year engines with the requirements specified in Part 1065.[13]

By letter dated June 13, 2014, CARB submitted a request to EPA pursuant to section 209(e) of the CAA for authorization of its 2011 SORE amendments. CARB seeks EPA's confirmation that the 2011 SORE amendments fall within the scope of

[1] The federal term ''nonroad'' and the California term ''off-road'' are used interchangeably.

[2] 60 FR 37440 (July 20, 1995).

[3] 65 FR 69763 (November 20, 2000).

[4] 65 FR 69767 (November 20, 2000); 68 FR 65702 (November 21, 2003).

[5] 75 FR 8056 (February 23, 2010).

[6] 71 FR 75536 (December 15, 2006).

[7] The specific regulatory text for the 2008 amendments is codified at title 13, California Code of Regulations (CCR), sections 2401, 2403, 2404, 2405, 2406, 2408, 2408.1 and 2409. California's Office of Administrative Law formally approved the rulemaking on April 5, 2010 and the regulations became effective on May 5, 2010.

[8] *See* 79 FR 30610 (May 28, 2014).

[9] *See* EPA–HQ–OAR–2014–0535–0007, ''Enclosure 5 CARB Resolution 11–41'', and EPA–HQ–OAR–2014–0535–0008, ''Enclosure 6 Executive Order R–12–005''.

[10] *Id.*

[11] *See* EPA–HQ–OAR–2014–0535–0001, ''2013–13–14 Auth Support Document SORE 2011''.

[12] *Id.*at 11.

[13] *Id.*at 11.

EPA's previous authorizations,[14] or, in the alternate, a full authorization for those amendments.

II. California's Off-Road CI Engine Regulations

Off-road CI engines are used in tractors, excavators, dozers, scrapers, portable generators, transport refrigeration units, irrigation pumps, welders, compressors, scrubbers, and sweepers.[15] In 1992, CARB approved a regulation to control exhaust emissions from heavy-duty off-road CI engines 175 hp and above.[16] CARB requested that EPA grant authorization and it was granted in 1995.[17] In 2000 and in 2004–2005, CARB amended or adopted emission standards and accompanying test procedures that affected three power categories of off road CI engines. The 2000 rulemaking generally harmonized California's emission standards and test procedures to federal standards that EPA promulgated in 1998 for the same nonroad CI engine categories (Tier 1 through Tier 3).[18] The 2004–2005 CARB rulemaking generally harmonized California's Tier 4 standards to the federal Tier 4 standards for these same off-road CI engines that EPA adopted in 2004.[19] In February 2010, EPA confirmed that the 2000 amendments to the smallest category of engines (less than 19kW) were within the scope of the previously granted authorization. EPA further granted full authorizations for the 2004–2005 amendments as they affected new off-road CI engines less than 19kW, and for the 2000 and 2004–2005 amendments as they affected new off-road CI engines for the other two power categories (19kW–130kW and greater than 130kW).[20]

CARB approved the Tier 4 amendments at issue in this notice on December 16, 2011, and adopted them on October 25, 2012.[21] The 2011 Tier 4 amendments became operative on January 10, 2013.[22] The 2011 Tier 4 amendments enhance the harmonization of CARB's exhaust emission requirements for new off-road CI engines with the corresponding federal emissions requirements for nonroad CI engines set forth in Parts 1039, 1065, and 1068.[23] EPA most recently amended these Parts in 2011.[24] The 2011 Tier 4 amendments correct clerical errors, standardize measurement specifications, calibrations, and instrumentation, remove unnecessarily burdensome reporting requirements, and provide additional compliance flexibility options.[25] The 2011 Tier 4 amendments also incorporate EPA's anti-stockpiling provisions, which help ensure the realization of projected emission benefits, and also establish a new interim Tier 4 combined hydrocarbon plus oxides of nitrogen emission standard that has the potential to provide additional emission benefits.[26]

By letter dated June 13, 2014, CARB submitted a request to EPA pursuant to section 209(e) of the CAA for authorization of its 2011 Tier 4 amendments. CARB seeks EPA's confirmation that the 2011 Tier 4 amendments fall within the scope of EPA's previous authorizations, or, in the alternative, a full authorization for those amendments.

III. California's Exhaust Emission Certification Test Fuel for Off-Road Spark-Ignition Engines, Equipment, and Vehicles Regulations

Prior to the 2011 Certification Test Fuel amendments, California's SORE and Large Spark Ignition (LSI) test procedures allowed gasoline-fueled, spark-ignition engines to be tested for compliance with certification exhaust standards using either Indolene or Phase 2 California Reformulated Gasoline (CaRFG2) as an option to federally specified test fuels. Recreational marine engines were permitted to use CaRFG2, federal Indolene, or the fuel specified in Table 3 of Appendix A to 40 CFR Part 91, Subpart D. Off Highway Recreational Vehicles (OHRV) that were categorized as off-road motorcycles were required to certify using Indolene. OHRVs that were categorized as go-karts and specialty vehicles were allowed to certify using either Indolene or CaRFG2, and OHRVs that were categorized as all-terrain vehicles (ATVs) were generally required to use Indolene, but were allowed to certify using CaRFG2 in some circumstances.[27]

The initial SORE regulation and the 1993 amendments to the SORE regulation allowed manufacturers to utilize either Indolene or California Phase 1 fuel as test fuel for certification.[28] EPA granted California a full authorization for the initial SORE regulation and the 1993 amendments.[29] In 1994 CARB amended the SORE regulation to provide manufacturers the option to certify SORE engines using CaRFG2 that was consistent with the certification test fuel specified for on-road motor vehicles. EPA confirmed that the 1994 amendment was within the scope of the previously issued authorization for the SORE regulation and additionally confirmed that the 1995 and 1996 amendments to the SORE regulation fell within the scope of the initially granted SORE authorization.[30] Additional SORE amendments in 1998 were confirmed as within the scope of previous authorizations. EPA issued a full authorization for CARB's 2004 SORE amendments.[31] CARB has subsequently requested within-the-scope confirmation from EPA for a provision of the 2008 SORE amendment package that allows use of 10-percent ethanol-gasoline blend (E10) for SORE certification fuel. That request is currently pending with the EPA and a notice of decision is under review.[32]

The initial LSI regulation specified that the certified gasoline test fuels for LSI engines were either Indolene or CaRFG2. EPA granted California a new authorization for the initial LSI regulation on May 15, 2006.[33] CARB amended the LSI regulation in 2006 and EPA granted CARB a full authorization for those amendments in 2012.[34]

The initial CARB Marine SI Engine regulation applicable to 2001 and later model year outboard SI marine engines and personal watercraft engines established test procedures that were virtually identical to those in the federal SI Marine Engine regulations. In 2002 CARB adopted regulations establishing exhaust emission standards and related certification and test procedures for 2003 and later model year SI inboard

[14] EPA's most recent authorizations for CARB's SORE regulations can be found at 71 FR 75536 (December 15, 2006) and 75 FR 8056 (February 23, 2010).

[15] *See* EPA–HQ–OAR–2014–0535–0001, ''2013–13–14 Auth Support Document SORE 2011'' at 4.

[16] *Id.*

[17] 60 FR 37440 (July 5, 1995).

[18] *See* EPA–HQ–OAR–2014–0535–0001, ''2013–13–14 Auth Support Document SORE 2011'' at 5.

[19] *Id.*

[20] 75 FR 8056 (February 23, 2010).

[21] *See* EPA–HQ–OAR–2014–0535–0007, ''Enclosure 5 CARB Resolution 11–41'', and EPA–HQ–OAR–2014–0535–0008, ''Enclosure 6 Executive Order R–12–005''.

[22] *Id.*

[23] *See* EPA–HQ–OAR–2014–0535–0001, ''2013–13–14 Auth Support Document SORE 2011'' at 12.

[24] 76 FR 37977 (June 28, 2011).

[25] *See* EPA–HQ–OAR–2014–0535–0001, ''2013–13–14 Auth Support Document SORE 2011'' at 13–18.

[26] *Id.* at 2.

[27] *See* EPA–HQ–OAR–2014–0535–0001, ''2013–13–14 Auth Support Document SORE 2011'' at 9.

[28] *Id.* at 8.

[29] 60 FR 37440 (July 20, 1995).

[30] 65 FR 69763 (Nov. 20, 2000).

[31] *See* EPA–HQ–OAR–2014–0535–0001, ''2013–13–14 Auth Support Document SORE 2011'' at 8.

[32] The 2008 SORE amendments initial notice for public hearing and comment can be found at 79 FR 30610 (May 28, 2014).

[33] 71 FR 29623 (May 23, 2006).

[34] 77 FR 20388 (April 4, 2012).

and sterndrive marine engines that specified the same certification test fuels as those applicable to outboard engines and personal water craft.[35] EPA granted California an authorization for these regulations in 2007.[36] CARB amended the Marine SI Engine regulations in 2006 and EPA granted an authorization for those amendments in 2011.[37]

EPA granted California a new authorization for the initial OHRV regulation in 1996,[38] and confirmed that 1996 amendments to the OHRV regulation were within the scope of the initial authorization in 2000.[39] In 2014, EPA granted new authorizations, confirmed that amendments were within the scope of the previously issued authorizations, or confirmed that no authorization action was required for CARB's 1999, 2003, and 2006 amendments to the OHRV regulation.[40]

The 2011 Certification Test Fuel amendments modified the certification test fuel requirements for off-road spark ignition, gasoline-fueled engines to allow the use of 10-percent ethanol-blend of gasoline (E10) as a certification fuel. The use of the E10 certification fuel is allowed as an option for certification exhaust emission testing of new gasoline-fueled SORE, LSI, Recreational Marine, and OHRV off-road categories from the 2013 through 2019 model years, and is mandatory for certification exhaust emission testing of these categories beginning with the 2020 model year.[41]

By letter dated June 13, 2014, CARB submitted a request to EPA pursuant to section 209(e) of the CAA for authorization of its 2011 Certification Test Fuel amendments. CARB seeks EPA's confirmation that the 2011 Certification Test Fuel amendments fall within the scope of EPA's previous authorizations, or, in the alternate, a full authorization for those amendments.

IV. Clean Air Act Nonroad Engine and Vehicle Authorizations

Section 209(e)(1) of the CAA prohibits states and local governments from adopting or attempting to enforce any standard or requirement relating to the control of emissions from new nonroad vehicles or engines. The Act also preempts states from adopting and enforcing standards and other requirements related to the control of emissions from non-new nonroad engines or vehicles. Section 209(e)(2), however, requires the Administrator, after notice and opportunity for public hearing, to authorize California to adopt and enforce standards and other requirements relating to the control of emissions from such vehicles or engines if California determines that California standards will be, in the aggregate, at least as protective of public health and welfare as applicable Federal standards. However, EPA shall not grant such authorization if it finds that (1) the determination of California is arbitrary and capricious; (2) California does not need such California standards to meet compelling and extraordinary conditions; or (3) California standards and accompanying enforcement procedures are not consistent with [CAA section 209].[42] In addition, other states with air quality attainment plans may adopt and enforce such regulations if the standards and the implementation and enforcement procedures are identical to California's standards. On July 20, 1994, EPA promulgated a rule that sets forth, among other things, regulations providing the criteria, as found in section 209(e)(2), which EPA must consider before granting any California authorization request for new nonroad engine or vehicle emission standards.[43] EPA revised these regulations in 1997.[44] As stated in the preamble to the 1994 rule, EPA has historically interpreted the section 209(e)(2)(iii) ''consistency'' inquiry to require, at minimum, that California standards and enforcement procedures be consistent with section 209(a), section 209(e)(1), and section 209(b)(1)(C) (as EPA has interpreted that subsection in the context of section 209(b) motor vehicle waivers).[45]

In order to be consistent with section 209(a), California's nonroad standards and enforcement procedures must not apply to new motor vehicles or new motor vehicle engines. To be consistent with section 209(e)(1), California's nonroad standards and enforcement procedures must not attempt to regulate engine categories that are permanently preempted from state regulation. To determine consistency with section 209(b)(1)(C), EPA typically reviews nonroad authorization requests under the same ''consistency'' criteria that are applied to motor vehicle waiver requests. Pursuant to section 209(b)(1)(C), the Administrator shall not grant California a motor vehicle waiver if she finds that California ''standards and accompanying enforcement procedures are not consistent with [section 202(a)]'' of the Act. Previous decisions granting waivers and authorizations have noted that state standards and enforcement procedures are inconsistent with section 202(a) if: (1) There is inadequate lead time to permit the development of the necessary technology giving appropriate consideration to the cost of compliance within that time, or (2) the federal and state testing procedures impose inconsistent certification requirements.[46]

If California amends regulations that EPA has already authorized, California can seek EPA confirmation that the amendments are within the scope of the previous authorization. A within-the-scope confirmation, without a full authorization review, is permissible if three conditions are met.[47] First, the amended regulations must not undermine California's determination

[35] *See* EPA–HQ–OAR–2014–0535–0001, ''2013–13–14 Auth Support Document SORE 2011'' at 9.

[36] 72 FR 14546 (March 28, 2007).

[37] 76 FR 24872 (May 3, 2011).

[38] 61 FR 69093 (Dec. 31, 1996).

[39] 65 FR 69763 (Nov. 20, 2000).

[40] 79 FR 6584 (Feb. 14, 2014).

[41] *See* EPA–HQ–OAR–2014–0535–0001, ''2013–13–14 Auth Support Document SORE 2011'' at 18.

[42] EPA's review of California regulations under section 209 is not a broad review of the reasonableness of the regulations or its compatibility with all other laws. Sections 209(b) and 209(e) of the Clean Air Act limit EPA's authority to deny California requests for waivers and authorizations to the three criteria listed therein. As a result, EPA has consistently refrained from denying California's requests for waivers and authorizations based on any other criteria. In instances where the U.S. Court of Appeals has reviewed EPA decisions declining to deny waiver requests based on criteria not found in section 209(b), the Court has upheld and agreed with EPA's determination. *See Motor and Equipment Manufacturers Ass'n* v. *Nichols,* 142 F.3d 449, 462–63, 466–67 (D.C. Cir.1998), *Motor and Equipment Manufacturers Ass'n* v. *EPA,* 627 F.2d 1095, 1111, 1114–20 (D.C. Cir. 1979). *See also* 78 FR 58090, 58120 (September 20, 2013).

[43] 59 FR 36969 (July 20, 1994).

[44] 62 FR 67733 (December 30, 1997). The applicable regulations, now in 40 CFR part 1074, subpart B, § 1074.105, provide:

(a) The Administrator will grant the authorization if California determines that its standards will be, in the aggregate, at least as protective of public health and welfare as otherwise applicable federal standards.

(b) The authorization will not be granted if the Administrator finds that any of the following are true:

(1) California's determination is arbitrary and capricious.

(2) California does not need such standards to meet compelling and extraordinary conditions.

(3) The California standards and accompanying enforcement procedures are not consistent with section 209 of the Act.

(c) In considering any request to authorize California to adopt or enforce standards or other requirements relating to the control of emissions from new nonroad spark-ignition engines smaller than 50 horsepower, the Administrator will give appropriate consideration to safety factors (including the potential increased risk of burn or fire) associated with compliance with the California standard.

[45] 59 FR 36969 (July 20, 1994).

[46] *Id. See also* 78 FR 58090, 58092 (September 20, 2013).

[47] *See* 78 FR 38970, 38972 (June 28, 2013).

that its standards, in the aggregate, are as protective of public health and welfare as applicable federal standards. Second, the amended regulations must not affect consistency with section 202(a) of the Act. Third, the amended regulations must not raise any ''new issues'' affecting EPA's prior authorizations.

V. EPA's Request for Comments

As stated above, EPA is offering the opportunity for a public hearing, and is requesting written comment on issues relevant to a within-the-scope analysis. Specifically, we request comment on whether California's 2011 SORE amendments, 2011 Tier 4 amendments, and 2011 Certification Test Fuel amendments: (1) Undermine California's previous determination that its standards, in the aggregate, are at least as protective of public health and welfare as comparable federal standards; (2) affect the consistency of California's requirements with section 209 of the Act; or (3) raise any other new issues affecting EPA's previous waiver or authorization determinations.

Should any party believe that the amendments are not within the scope of the previous authorizations, EPA also requests comment on whether the 2011 SORE amendments, 2011 Tier 4 amendments, and 2011 Certification Test Fuel amendments meet the criteria for a full authorization. Specifically, we request comment on: (a) Whether CARB's determination that its standards, in the aggregate, are at least as protective of public health and welfare as applicable federal standards is arbitrary and capricious; (b) whether California needs such standards to meet compelling and extraordinary conditions; and (c) whether California's standards and accompanying enforcement procedures are consistent with section 209 of the Act.

VI. Procedures for Public Participation

If a hearing is held, the Agency will make a verbatim record of the proceedings. Interested parties may arrange with the reporter at the hearing to obtain a copy of the transcript at their own expense. Regardless of whether a public hearing is held, EPA will keep the record open until February 16, 2015. Upon expiration of the comment period, the Administrator will render a decision on CARB's request based on the record from the public hearing, if any, all relevant written submissions, and other information that she deems pertinent. All information will be available for inspection at the EPA Air Docket No. EPA–HQ–OAR–2014–0535.

Persons with comments containing proprietary information must distinguish such information from other comments to the greatest extent possible and label it as ''Confidential Business Information'' (CBI). If a person making comments wants EPA to base its decision on a submission labeled as CBI, then a non-confidential version of the document that summarizes the key data or information should be submitted to the public docket. To ensure that proprietary information is not inadvertently placed in the public docket, submissions containing such information should be sent directly to the contact person listed above and not to the public docket. Information covered by a claim of confidentiality will be disclosed by EPA only to the extent allowed, and according to the procedures set forth in 40 CFR Part 2. If no claim of confidentiality accompanies the submission when EPA receives it, EPA will make it available to the public without further notice to the person making comments.

Dated: November 12, 2014.

Christopher Grundler,

Director, Office of Transportation and Air Quality, Office of Air and Radiation.

[FR Doc. 2014–27644 Filed 11–20–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[Petition No. IX–2013–1; FRL–9919–46–Region 9]

Petition on Clean Air Act Title V Permit; Gateway Generating Station; Antioch, CA

AGENCY: United States Environmental Protection Agency.

ACTION: Notice of final action.

SUMMARY: Pursuant to Clean Air Act (CAA) section 505(b) and 40 CFR 70.8(d), the United States Environmental Protection Agency (EPA) Administrator signed an Order, dated October 15, 2014, denying a petition to object to a CAA title V operating permit proposed by the Bay Area Air Quality Management District (BAAQMD) for the Gateway Generating Station, LLC facility in Antioch, California (Gateway). The Order constitutes a final action on the petition submitted by the Wild Equity Institute (Petitioner) dated September 3, 2013 requesting that the EPA Administrator object to the proposed title V permit for Gateway. Pursuant to section 505(b) of the CAA, a petitioner may seek judicial review in the United States Court of Appeals for the appropriate circuit of those portions of the petition that EPA denied. Any petition for review shall be filed within 60 days from the date this notice appears in the **Federal Register**, pursuant to section 307 of the CAA.

DATES: The EPA Administrator signed an Order, dated October 15, 2014, denying a petition to object to the CAA title V operating permit proposed by the BAAQMD for Gateway. Pursuant to section 307(b)(1) of the Clean Air Act, 42 U.S.C. 7607(b)(1), judicial review of this final permit decision, to the extent it is available, may be sought by filing a petition for review in the United States Court of Appeals for the Ninth Circuit within 60 days of November 21, 2014.

ADDRESSES: Copies of the Order, the petition, and all pertinent information relating thereto are on file at the following location: EPA Region 9, Air Division, 75 Hawthorne Street, San Francisco, California 94105. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view copies of the final Order, petition, and other supporting information. You may view the hard copies Monday through Friday, from 9 a.m. to 4 p.m., excluding Federal holidays. If you wish to examine these documents, you should make an appointment at least 48 hours before the visiting day. The final Order is also available electronically at the following Web site: *http://www.epa.gov/region07/air/title5/petitiondb/petitiondb.htm.*

FOR FURTHER INFORMATION CONTACT: Gerardo Rios, Air Permits Office, EPA Region 9, at (415) 972–3974 or *rios.gerardo@epa.gov.*

SUPPLEMENTARY INFORMATION: The CAA affords the EPA a 45-day period to review and, as appropriate, object to operating permits proposed by state permitting authorities under title V of the CAA, 42 U.S.C. 7661–7661f. Section 505(b)(2) of the CAA and 40 CFR 70.8(d) authorize any person to petition the EPA Administrator to object to a title V operating permit within 60 days after the expiration of the EPA's 45-day review period if the EPA has not objected on its own initiative. Petitions must be based only on objections to the permit that were raised with reasonable specificity during the public comment period provided by the state, unless the petitioner demonstrates that it was impracticable to raise these issues during the comment period or the grounds for the issues arose after this period.

The Petitioner submitted a petition regarding Gateway dated September 3,

2013, requesting that the EPA object to the proposed CAA title V operating permit for Gateway issued by the BAAQMD, identified as Major Facility Review Permit, Facility #B8143. The Petitioner alleged that the permit was not consistent with CAA title V requirements because the EPA failed to obtain incidental take authorization and take other actions under the Endangered Species Act for ''listed species affected by'' the facility. The BAAQMD issued a final title V permit for Gateway on October 30, 2013.

On October 15, 2014, the EPA Administrator issued an Order denying the title V petition for Gateway. The Order explains EPA's rationale for denying the petition.

Dated: October 29, 2014.

Jared Blumenfeld,

Regional Administrator, Region IX.

[FR Doc. 2014–27641 Filed 11–20–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9018–1]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/compliance/nepa/*.

Weekly receipt of Environmental Impact Statements.

Filed 11/10/2014 Through 11/14/2014. 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. 20140330, Final EIS, BLM, OR, West Eugene Wetlands Resource Management Plan, review period ends: 12/22/2014, Contact: Panchita Paulete 541–683–6976.

EIS No. 20140331, Draft EIS, FHWA, NY, NJ, Cross Harbor Freight Program, comment period ends: 02/27/2015, Contact: Jonathan McDade 518–431–4127.

Amended Notices

EIS No. 20140198, Draft EIS, NMFS, WA, Two Joint State and Tribal Resource Management Plans for Puget Sound Salmon and Steelhead Hatchery Programs, comment period ends: 01/23/2015, Contact: Steve Leider 360–753–4650.

Revision to the FR Notice Published 10/03/2014; Extending the Comment Period from 11/24/2014 to 01/23/2015.

EIS No. 20140278, Draft EIS, BLM, CA, Desert Renewable Energy Conservation Plan (DRECP), comment period ends: 02/23/2015, Contact: Vicki Campbell 916–978–4401.

Revision to the FR Notice Published 09/26/2014; Extending the Comment Period from 01/09/2015 to 02/23/2015.

Dated: November 18, 2014.

Cliff Rader,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2014–27633 Filed 11–20–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2014–0829; FRL–9919–22]

Pesticide Program Dialogue Committee; Notice of Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), EPA's Office of Pesticide Programs (OPP) is announcing a public meeting of the Pesticide Program Dialogue Committee (PPDC) on December 11–12, 2014. In addition, EPA is also announcing meetings on December 10, 2014, of the following PPDC workgroups: The Work Group on Integrated Pest Management and the Work Group on Pollinator Protection. These meetings provide advice and recommendations to the EPA Administrator on issues associated with pesticide regulatory development and reform initiatives, evolving public policy and program implementation issues, and science issues associated with evaluating and reducing risks from use of pesticides.

DATES: *Meeting:* The PPDC meeting will be held on Thursday, December 11, 2014, from 9 a.m. to 5 p.m., and Friday, December 12, 2014, from 9 a.m. to noon.

Work group meetings: On Wednesday, December 10, 2014, PPDC work group meetings are scheduled as follows: The Work Group on Integrated Pest Management, from 9 a.m. to 11:30 a.m., and the Work Group on Pollinator Protection, from 1 p.m. to 4 p.m.

14P–0253

Agenda: A draft agenda will be posted on or before December 2, 2014.

Accommodations requests: To request accommodation of a disability, please contact the person listed under **FOR FURTHER INFORMATON CONTACT**, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

ADDRESSES: The PPDC meeting and both PPDC Work Group meetings will be held at 1 Potomac Yard South, 2777 S. Crystal Dr., Arlington, VA, in the lobby-level Conference Center.

EPA's Potomac Yard South Bldg. is approximately 1 mile from the Crystal City Metro Station.

FOR FURTHER INFORMATION CONTACT: Margie Fehrenbach, Office of Pesticide Programs (7501P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–4775; email address: *fehrenbach.margie@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you work in in agricultural settings or if you are concerned about implementation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the Federal Food, Drug, and Cosmetic Act (FFDCA); and the amendments to both of these major pesticide laws by the Food Quality Protection Act (FQPA); the Pesticide Registration Improvement Act (PRIA); and the Endangered Species Act (ESA). Potentially affected entities may include, but are not limited to: Agricultural workers and farmers; pesticide industry and trade associations; environmental, consumer, and farm worker groups; pesticide users and growers; animal rights groups; pest consultants; State, local, and tribal governments; academia; public health organizations; and the public. If you have questions regarding the applicability of this action to a particular entity, contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2014–0829, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal

holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

II. Background

OPP is entrusted with responsibility to help ensure the safety of the American food supply, the education and protection from unreasonable risk of those who apply or are exposed to pesticides occupationally or through use of products, and general protection of the environment and special ecosystems from potential risks posed by pesticides.

The charter for EPA's PPDC was established under FACA, Public Law 92–463 (5 U.S.C. Appendix), in September 1995, and has been renewed every 2 years since that time. PPDC's charter was renewed October 25, 2013, for another 2-year period. The purpose of PPDC is to provide advice and recommendations to the EPA Administrator on issues associated with pesticide regulatory development and reform initiatives, evolving public policy and program implementation issues, and science issues associated with evaluating and reducing risks from use of pesticides. It is determined that PPDC is in the public interest in connection with the performance of duties imposed on the Agency by law. The following sectors are represented on the current PPDC: Environmental/public interest and animal rights groups; farm worker organizations; pesticide industry and trade associations; pesticide user, grower, and commodity groups; Federal and State/local/tribal governments; the general public; academia; and public health organizations.

Copies of the PPDC charter are filed with appropriate committees of Congress and the Library of Congress and are available upon request.

III. How can I request to participate in this meeting?

PPDC meetings are free, open to the public, and no advance registration required. Public comments may be made during the public comment session of each meeting or in writing to the person listed under **FOR FURTHER INFORMATION CONTACT**.

Authority: 7 U.S.C. 136 *et seq.*

Dated: November 13, 2014.

Jack S. Housenger,

Director, Office of Pesticide Programs.

[FR Doc. 2014–27635 Filed 11–20–14; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[9919–45–OAR]

Technical Research Workshop Supporting EPA and NHTSA Phase 2 Standards for MD/HD Greenhouse Gas and Fuel Efficiency

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public workshop.

SUMMARY: EPA and NHTSA are sponsoring a technical workshop on December 10 and 11, 2014, at Southwest Research Institute (SwRI) in San Antonio, Texas. SwRI researchers will present technical work completed under the direction of EPA and NHTSA to assist in developing Phase 2 medium- and heavy-duty GHG and fuel efficiency standards.

DATES: The workshop will be held at Southwest Research Institute December 10 and 11, 2014.

ADDRESSES: The workshop will be held at Southwest Research Institute, 6220 Culebra Road, San Antonio, Texas 78238, 210–684–5111. A complimentary shuttle will be provided to and from Courtyard by Marriott San Antonio SeaWorld/Westover Hills, 11605 State Hwy 151, San Antonio, TX 78251, (210) 509–3700.

FOR FURTHER INFORMATION CONTACT: Houshun Zhang, Office of Transportation and Air Quality, U.S. Environmental Protection Agency, (734) 214–4214. *zhang.houshun@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA and NHTSA are sponsoring a technical workshop on December 10 and 11, 2014, at Southwest Research Institute (SwRI) in San Antonio, Texas. SwRI researchers will present technical work completed under the direction of EPA and NHTSA to assist in developing Phase 2 medium- and heavy-duty GHG and fuel efficiency standards.

This technical work includes testing conducted over-the-road and on heavy-duty chassis dynamometers, powertrain test cells, and engine test cells. This work has been conducted to advance test procedure development and validate refinements that agencies have been considering for the greenhouse gas emissions model (GEM) used for heavy-duty vehicle certification. Aerodynamic tractor testing via both coast-down and constant-speed test procedures will also be presented, in addition to results from recent heavy-duty engine and vehicle technology modeling. SwRI will also describe simulation studies to look at the potential fuel saving performance of numerous MD/HD engine and vehicle technologies.

This workshop will not include discussion of policy considerations such as Phase 2 program stringency or program structure. Rather, this workshop is an opportunity for interested stakeholders and individuals to learn more about recent EPA and NHTSA sponsored technical research, to engage directly with the SwRI researchers who have been conducting this work, and to provide initial feedback on work conducted to date.

All interested parties are welcome to attend. See *http://epa.gov/otaq/climate/regs-heavy-duty.htm* for the agenda, schedule, and information regarding online registration. There is no registration fee.

Dated: November 12, 2014.

Christopher Grundler,

Director, Office of Transportation and Air Quality, Office of Air and Radiation.

[FR Doc. 2014–27638 Filed 11–20–14; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0132]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communication Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information

collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before January 20, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0132.

Title: Supplemental Information—72–76 MHz Operational Fixed Stations, FCC Form 1068A.

Form No.: FCC Form 1068A.

Type of Review: Extension of a currently approved collection.

Respondents: Individuals or household; state, local or tribal government; business or other for-profit entities; not-for-profit institutions.

Number of Respondents and Responses: 300 respondents and 300 responses.

Estimated Time per Response: 30 minutes.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in 47 CFR 90.257 of the Commission's rules and the Communications Act of 1934, as amended.

Total Annual Burden: 150 hours.

Total Annual Cost: No costs.

Privacy Act Impact Assessment: Yes. The FCC has a System of Records Notice (SORN), FCC/WTB–1, ''Wireless Services Licensing Records'', to cover the personally identifiable information affected by these information collection requirements. At this time, the Commission (FCC) is not required to complete a Privacy Impact Assessment.

Nature and Extent of Confidentiality: In general, there is no need for confidentiality. On a case by case basis, the Commission may be required to withhold from disclosure certain information about the location, character, or ownership of a historic property, including traditional religious sites.

Needs and Uses: FCC rules require that the applicant agrees to eliminate any harmful Interference caused by the operation to TV reception on either channel 4 or 5 that might develop. This form is required by the Communications Act of 1934, as amended; International Treaties and FCC Rules 47 CFR 90.257.

FCC staff will use the data to determine if the information submitted will meet the FCC Rule requirements for the assignment of frequencies in the 72–76 MHz band.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of the Managing Director.

[FR Doc. 2014–27526 Filed 11–20–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0139 and 3060–xxxx]

Information Collections Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before January 20, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0139.

Title: Application for Antenna Structure Registration.

Form Number: FCC Form 854.

Type of Review: Revision of a currently approved collection.

Respondents: Individuals or households, business or other for-profit entities, not-for-profit institutions, and State, local, or Tribal governments.

Number of Respondents and Responses: 2,400 respondents; 57,000 responses.

Estimated Time per Response: .33 hours to 2.5 hours.

Frequency of Response: On occasion reporting requirement, recordkeeping requirement and third party disclosure reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in Sections 1, 2, 4(i), 303, and 309(j) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 303, and 309(j), Section 102(C) of the National Environmental Policy Act of 1969, as amended, 42 U.S.C. 4332(C), and Section 1506.6 of the regulations of the Council on Environmental Quality, 40 CFR 1506.6.

Total Annual Burden: 24,222 hours.

Total Annual Cost: $1,176,375.

Privacy Act Impact Assessment: Yes. This information collection contains personally identifiable information on individuals which is subject to the Privacy Act of 1974. Information on the FCC Form 854 is maintained in the Commission's System of Records, FCC/WTB–1, ''Wireless Services Licensing Records.'' These licensee records are publicly available and routinely used in accordance of subsection b of the Privacy Act, 5 U.S.C. 552a(b), as amended. Taxpayer Identification Numbers (TINs) and materials that are

afforded confidential treatment pursuant to a request made under 47 CFR 0.459 of the Commission's rules will not be available for public inspection.

Nature and Extent of Confidentiality: Respondents may request materials or information submitted to the Commission be withheld from public inspection under 47 CFR 0.459 of the Commission's rules.

The Commission has in place the following policy and procedures for records retention and disposal: Records will be actively maintained as long as the entity remains a tower owner. Paper records will be archived after being keyed or scanned into the Antenna Structure Registration (ASR) database and destroyed when twelve (12) years old.

Needs and Uses: As discussed below, the Commission is revising the FCC Form 854 to implement measures adopted in a recent Report and Order, and is seeking Office of Management and Budget (OMB) approval for this information collection as revised. The Commission is also reporting an adjustment in the annual burden and annual cost due to an increase in the number of responses and minor increases in hourly wages. After the comment period, the Commission will submit the revised information collection to OMB to obtain the full three year clearance.

The purpose of the FCC Form 854 is to register antenna structures (radio towers) that are used for communication services regulated by the Commission; to make changes to existing antenna structure registrations or pending applications for registration; or to notify the Commission of the completion of construction or dismantlement of such structures, as required by Title 47 of the Code of Federal Regulations (CFR), Chapter 1. In addition, for proposed new antenna structures, the FCC Form 854 is used to facilitate a pre-application public notification process, including a required 30-day period of local and national notice to provide members of the public with a meaningful opportunity to comment on the environmental effects of proposed antenna structures that require registration with the Commission.

The Commission is revising this current information collection due to the adoption of FCC 14–153, Report and Order, which altered the public notification process for certain temporary towers. In the Report and Order, the Commission adopted a narrow exemption from the public notification process for proposed temporary antenna structures meeting defined criteria, including limits on the size and duration of the installation, that greatly reduce the likelihood of any significant environmental effects. Specifically, the exemption from the environmental notification process applies only to temporary antenna structures that: (1) Do not require an Environmental Assessment under the Commission's rules; (2) will be in place for 60 days or less; (3) require notice of construction to the Federal Aviation Administration (FAA); (4) do not require marking or lighting under FAA regulations; (5) will be less than 200 feet above ground level; and (6) will involve minimal or no ground excavation. The Report and Order also provided that applicants may request and obtain a single extension of up to 60 additional days upon an appropriate showing.

As a result, the FCC Form 854 is being revised to permit applicants to indicate that they are claiming the new exemption and certify that they meet the relevant requirements, and to request an extension. These changes are necessary to implement the new exemption from the public notification process for temporary antenna structures. They will therefore enable the Commission to more efficiently process antenna structure registrations and, by allowing licensees to deploy covered temporary structures without first having to complete the notification process, will enable them to more effectively respond to emergencies, natural disasters, and other planned and unplanned short-term spikes in demand without undermining the purposes of the notification process.

OMB Control Number: 3060–xxxx.

Title: Acceleration of Broadband Deployment by Improving Wireless Facilities Siting Policies.

Form Number: N/A.

Type of Review: New collection.

Respondents: Individuals or households, business or other for-profit entities, not-for-profit institutions and State, local or Tribal governments.

Number of Respondents: 1,350 respondents; 3,597 responses.

Estimated Time per Response: .5 hours to 1 hour.

Frequency of Response: Third-party disclosure reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in Sections 1, 2, 4(i), 7, 201, 301, 303, and 309 of the Communications Act of 1934, as amended, and Sections 6003, 6213, and 6409(a) of the Middle Class Tax Relief and Job Creation Act of 2012, Pub. L. No. 112–96, 126 Stat. 156, 47 U.S.C. 151, 152, 154(i), 157, 201, 301, 303, 309, 1403, 1433, and 1455(a).

Total Annual Burden: 3,535 hours.

Total Annual Cost: None.

Privacy Impact Assessment: This information collection may affect individuals or households. However, the information collection consists of third-party disclosures in which the Commission has no direct involvement. Personally identifiable information (PII) is not being collected by, made available to, or made accessible by the Commission. There are no additional impacts under the Privacy Act.

Nature and Extent of Confidentiality: No known confidentiality between third parties.

Needs and Uses: The Commission will submit this information collection for approval after the comment period to obtain the full three year clearance from the Office of Management and Budget (OMB). The Commission is requesting OMB approval for new disclosure requirements pertaining to Subpart CC of Part 1 of the Commission's rules. This Subpart was adopted to implement and enforce Section 6409(a) of the Middle Class Tax Relief and Job Creation Act of 2012. Section 6409(a) provides, in part, that ''a State or local government may not deny, and shall approve, any eligible facilities request for a modification of an existing wireless tower or base station that does not substantially change the physical dimensions of such tower or base station.'' 47 U.S.C. 1455(a)(1). In Subpart CC, the Commission adopted definitions of ambiguous terms, procedural requirements, and remedies to provide guidance to all stakeholders on the proper interpretation of the provision and to enforce its requirements, reducing delays in the review process for wireless infrastructure modifications and facilitating the rapid deployment of wireless infrastructure.

The following are the information collection requirements in connection with Subpart CC of Part 1 of the Commission's rules:

- 47 CFR 1.40001(c)(3)(i)—To toll the 60-day review timeframe on grounds that an application is incomplete, the reviewing State or local government must provide written notice to the applicant within 30 days of receipt of the application, clearly and specifically delineating all missing documents or information. Such delineated information is limited to documents or information meeting the standard under paragraph (c)(1) of Section 1.140001.
- 47 CFR 1.140001(c)(3)(iii)—Following a supplemental submission from the applicant, the State or local

government will have 10 days to notify the applicant in writing if the supplemental submission did not provide the information identified in the State or local government's original notice delineating missing information. The timeframe for review is tolled in the case of second or subsequent notices of incompleteness pursuant to the procedures identified in paragraph (c)(3). Second or subsequent notices of incompleteness may not specify missing documents or information that were not delineated in the original notice of incompleteness.

• 47 CFR 1.140001(c)(4)—If a request is deemed granted because of a failure to timely approve or deny the request, the deemed grant does not become effective until the applicant notifies the applicable reviewing authority in writing after the review period has expired (accounting for any tolling) that the application has been deemed granted.

These collections are necessary to effectuate the rule changes that implement and enforce the requirements of Section 6409(a).

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of the Managing Director.

[FR Doc. 2014–27527 Filed 11–20–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0600]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before January 20, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0600.

Title: Application to Participate in an FCC Auction, FCC 175.

Form Number: FCC Form 175.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, not-for-profit institutions, and state, local or tribal governments.

Estimated Number of Respondents and Responses: 500 respondents and 500 responses.

Estimated Time per Response: 90 minutes (estimated average time for respondents to report information requested on FCC Form 175).

Frequency of Response: On occasion reporting requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for the currently approved information collection is contained in sections 154(i), 309(j)(5), and 1404 of the Communications Act, as amended, 47 U.S.C. sections 4(i), 309(j)(5), 1404, and sections 1.2105, 1.2110, 1.2112, 2.106, US note 91, and 27.1134(f) of the Commission's rules, 47 CFR sections 1.2105, 1.2110, 1.2112, 2.106, US note 91, and 27.1134(f).

Estimated Total Annual Burden: 750 hours.

Total Annual Costs: No costs.

Nature and Extent of Confidentiality: Information collected on FCC Form 175 is made available for public inspection, and the Commission is not requesting that respondents submit confidential information on FCC Form 175. Respondents seeking to have information collected on FCC Form 175 withheld from public inspection may request confidential treatment of such information pursuant to section 0.459 of the Commission's rules, 47 CFR Section 0.459.

Privacy Act Impact Assessment: No impact(s).

Needs and Uses: A request for extension of this information collection (no change in requirements) will be submitted to the Office of Management and Budget (OMB) after this 60-day comment period in order to obtain the full three year clearance from OMB. The Commission's auction rules and requirements are designed to ensure that the competitive bidding process is limited to serious qualified applicants, deter possible abuse of the bidding and licensing process, and enhance the use of competitive bidding to assign Commission licenses in furtherance of the public interest. The information collected on FCC Form 175 is used by the Commission to determine if an applicant is legally, technically, and financially qualified to participate in a Commission auction. Additionally, if an applicant applies for status as a particular type of auction participant pursuant to Commission rules, the Commission uses information collected on Form 175 to determine whether the applicant is eligible for the status requested. Commission staff reviews the information collected on FCC Form 175 for a particular auction as part of the pre-auction process, prior to the auction being held. Staff determines whether each applicant satisfies the Commission's requirements to participate in the auction and, if applicable, is eligible for the status as a particular type of auction participant it requested. 47 CFR sections 2.106, US note 91 and 27.1134(f) require commercial licensees in the 1755–1780 MHz band to operate on a co-equal, primary operations with Federal systems within specified geographic zones and require such licensees to accept interference from Federal systems as long as such systems remain in the band. To implement these requirements, an applicant in any auction for licenses in the 1755–1780 MHz band will be required to submit a signed statement with its FCC Form 175 acknowledging these requirements. The information collected under this requirement will enable the

Commission to confirm that an auction applicant understands its specific obligations with respect to Federal incumbent users and systems in the 1755–1780 MHz frequency band should it ultimately become licensed in this band. The Commission plans to continue to use the FCC Form 175 for all upcoming spectrum auctions, collecting only the information necessary for each particular auction. Thus, the signed acknowledgement statement that is the subject of this collection will not be required for all auctions, and will only be used in auctions of licenses in the 1755–1780 MHz band.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of the Managing Director.

[FR Doc. 2014–27528 Filed 11–20–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1053]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before January 20, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1053.

Title: Two-Line Captioned Telephone Order, IP Captioned Telephone Service Declaratory Ruling; and Internet Protocol Captioned Telephone Service Reform Order, CG Docket Nos. 13–24 and 03–123.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 148,006 respondents; 556,010 responses.

Estimated Time per Response: 0.25 hours (15 minutes) to 8 hours.

Frequency of Response: Annual, every five years, on-going, and one-time reporting requirement; Recordkeeping requirement; Third party disclosure requirement.

Obligation To Respond: Required to obtain or retain benefits. The statutory authority for the information collection requirements is found at Sec. 225 [47 U.S.C. 225] Telecommunications Services for Hearing-Impaired Individuals; The Americans with Disabilities Act of 1990, (ADA), Pub. L. 101–336, 104 Stat. 327, 366–69, was enacted on July 26, 1990.

Total Annual Burden: 399,072 hours.

Total Annual Cost: $1,680,000.

Nature and Extent of Confidentiality: An assurance of confidentiality is not offered because this information collection does not require the collection of personally identifiable information by the FCC from individuals.

Privacy Impact Assessment: No impact(s).

Needs and Uses: On August 1, 2003, the Commission released Telecommunication Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities, CC Docket No. 98–67, Declaratory Ruling, 68 FR 55898, September 28, 2003, clarifying that one-line captioned telephone voice carry over (VCO) service is a type of telecommunications relay service (TRS) and that eligible providers of such services are eligible to recover their costs from the Interstate TRS Fund (Fund) in accordance with section 225 of the Communications Act. The Commission also clarified that certain TRS mandatory minimum standards do not apply to one-line captioned telephone VCO service and waived 47 CFR 64.604(a)(1) and (a)(3) for all current and future captioned telephone VCO service providers, for the same period of time beginning August 1, 2003. The waivers were contingent on the filing of annual reports. On July 19, 2005, the Commission released Telecommunication Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities, CC Docket No. 98–67 and CG Docket No. 03–123, Order, 70 FR 54294, September 14, 2005, clarifying that two-line captioned telephone VCO service, like one-line captioned telephone VCO service, is a type of TRS eligible for compensation from the Fund.

On January 11, 2007, the Commission released Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities, CG Docket No. 03–123, Declaratory Ruling, 72 FR 6960, February 14, 2007, granting a request for clarification that Internet Protocol (IP) captioned telephone relay service (IP CTS) is a type of TRS eligible for compensation from the Fund. The Commission also waived certain TRS mandatory minimum standards that do not apply to IP CTS, contingent on the filing of annual reports.

On August 26, 2013, the Commission issued Misuse of Internet Protocol (IP) Captioned Telephone Service; Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities, CG Docket Nos. 13–24 and 03–123, Report and Order, 78 FR 53684, August 30, 2013, to regulate practices relating to the marketing of IP CTS, impose certain requirements for the provision of this service, and mandate registration and certification of IP CTS users. On June 20, 2014, the D.C. Circuit vacated the rule prohibiting compensation to providers for minutes of use generated by equipment consumers received from providers for free or for less than $75 ($75 equipment

charge rule) and the rule requiring providers to maintain captions—off as the default setting for IP CTS equipment. Sorenson Communications, Inc. and CaptionCall, LLC v. FCC, 755 F.3d 702 (D.C. Cir. 2014) (D.C. Circuit IP CTS Order).

On August 22, 2014, the Commission issued Telecommunications Relay Services and Speech-to-Speech Services for Individuals with Hearing and Speech Disabilities; Waivers of iTRS Mandatory Minimum Standards, CG Docket No. 03–123, Report and Order, 79 FR 62875, October 21, 2014 (iTRS Waiver Order), to make permanent waivers of certain TRS mandatory minimum standards and eliminate waivers of other TRS mandatory minimum standards for IP CTS and CTS. The Commission also eliminated the requirement that IP CTS and CTS providers file annual reports regarding the TRS mandatory minimum standards.

This notice and request for comments pertains to revisions to the information collection requirements as a result of the iTRS Waiver Order eliminating the requirement that IP CTS and CTS providers file annual reports regarding the TRS mandatory minimum standards and as a result of the D.C. Circuit IP CTS Order vacating the $75 equipment charge rule and the rule requiring providers to maintain captions—off as the default setting for IP CTS equipment.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of the Managing Director.

[FR Doc. 2014–27524 Filed 11–20–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0927]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communication Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before January 20, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele at (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0927.

Title: Auditor's Annual Independence and Objectivity Certification.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 4 respondents; 4 responses.

Estimated Time per Response: 5 hours.

Frequency of Response: Annual reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. Sections 201(b), 219(b) and 220 of the Communications Act of 1934, as amended.

Total Annual Burden: 20 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality. However, respondents may request materials or information submitted to the Commission be withheld from public inspection under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: Section 64.904 requires certain local exchange carriers, in connection with their cost allocation manual filings and the accompanying financial reports the Commission prescribes under 47 U.S.C. 201(b), 219(b) and 220, to have an attest engagement performed by an independent auditor every two years, over the prior two year period. The attest engagement is to be performed in accordance with the attestation standards established by the American Institute of Certified Public Accountants (AICPA), except as otherwise directed by the Chief, Enforcement Bureau. The audit is to be conducted in compliance with generally accepted auditing standards (GAAS), except as otherwise directed by the Commission's Enforcement Bureau. The Responsible Accounting Office (RAO) letter requires that carriers' independent auditors:

(a) Disclose in writing all relationships between the auditor and its related entities and the carrier and its related entities that in the auditor's professional judgment may reasonably be thought to bear on independence;

(b) Confirm in writing that in its professional judgment it is independent of the carrier; and

(c) Discuss the auditor's independence.

The information is used by the Commission to determine whether the independent auditors are performing their audits independently and unbiased of the carrier they audit.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of the Managing Director.

[FR Doc. 2014–27525 Filed 11–20–14; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: Notice is hereby given of the final approval of a proposed information

collection by the Board of Governors of the Federal Reserve System (Board) under OMB delegated authority, as per 5 CFR 1320.16 (OMB Regulations on Controlling Paperwork Burdens on the Public). Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act Submission, supporting statements and approved collection of information instrument(s) are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Acting Clearance Officer—John Schmidt—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503.

Final approval under OMB delegated authority of the revision, without extension, of the following report:

Report title: Capital and Asset Report for Foreign Banking Organizations.

Agency form number: FR Y–7Q.

OMB control number: 7100–0125.[1]

Frequency: Quarterly and annually.

Reporters: Foreign Banking Organizations.

Estimated annual reporting hours: FR Y–7Q (quarterly): 763 hours; FR Y–7Q (annually): 65 hours.

Estimated average hours per response: FR Y–7Q (quarterly): 1.75 hours; FR Y–7Q (annually): 1.5 hours.

Number of respondents: FR Y–7Q (quarterly): 109; FR Y–7Q (annually): 43.

General description of report: This information collection is mandatory (12 U.S.C. 1844(c), 3106(c) and 3108)). Overall, the Federal Reserve does not consider these data to be confidential. However, individual respondents may request confidential treatment for any of these reports pursuant to sections (b)(4) and (b)(6) of the Freedom of Information Act (5 U.S.C. 522(b)(4) and (b)(6)). The applicability of these exemptions would need to be determined on a case-by-case basis.

Abstract: The FR Y–7Q collects consolidated regulatory capital information from all FBOs either quarterly or annually. The FR Y–7Q is filed quarterly by FBOs that have effectively elected to become financial holding companies (FHCs) and by FBOs that have total consolidated assets of $50 billion or more, regardless of FHC status. All other FBOs file the FR Y–7Q annually.

Current Actions: On June 18, 2014, the Federal Reserve published a notice in the **Federal Register** (79 FR 34753) requesting public comment for 60 days on the revision to the FR Y–7Q. The comment period for this notice expired on August 18, 2014. The Federal Reserve received one comment letter addressing the proposed revision of this information collection. The comment is summarized and addressed below.

Summary of Public Comment

The Federal Reserve received one comment letter regarding the proposed revision to the FR Y–7Q from one industry association. The commenter asked for an explanation of the instructions for calculating the proposed new data item, Total U.S. non-branch assets, and suggested an alternative approach for calculating the new item.

Detailed Discussion of Public Comment and Recommended Response

Under the proposal, in December 2014, the Federal Reserve proposed to collect a new data item, Total U.S. non-branch assets, to determine whether an FBO meets the threshold for formation of a U.S. IHC. This item would collect the sum of the total combined assets of a top-tier FBO's top-tier U.S. domiciled affiliates.[2] In situations where a top-tier U.S. domiciled affiliate is a parent of one or more subsidiaries, the total consolidated assets of the affiliate would include the assets of the affiliate and its subsidiaries, in accordance with U.S. Generally Accepted Accounting Principles (GAAP), and the total consolidated assets (or total assets, as applicable) of each top-tier U.S. domiciled affiliate would be combined. In situations where a top-tier U.S. domiciled subsidiary is not consolidated with the FBO for GAAP purposes, that entity would be accounted for under the equity method and the sum of the amount of the investments would be included in the sum of the total combined assets of top-tier U.S. domiciled affiliates.

The Federal Reserve received one comment on the proposed new item, Total U.S. non-branch assets. To produce the new item, the commenter suggested subtracting total U.S. branch and agency assets from an existing report item, Total combined assets of U.S. operations, net of intercompany balances and transaction between U.S. domiciled affiliates, branches, and agencies. However, the modification suggested by the commenter would result in FBOs understating their U.S. non-branch assets because the U.S. subsidiaries' asset exposures to affiliated U.S. branches and agencies would be excluded from the calculation. As described in the preamble to Regulation YY, the final rule requires an FBO to reduce its U.S. non-branch asset by the amount corresponding to any balances and transactions between any top tier U.S. subsidiaries that would be eliminated in consolidation.[3] However, the final rule does not permit an FBO to reduce its U.S. non-branch asset by the amount corresponding to balances and transactions between the U.S. subsidiaries and its U.S. branches and agencies or non-U.S. affiliates.[4]

After careful consideration of the suggested alternative and for the reasons discussed above, the Federal Reserve will implement the proposed line item without modification.

Board of Governors of the Federal Reserve System, November 17, 2014.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2014–27506 Filed 11–20–14; 8:45 am]

BILLING CODE 6210–01–P

[1] Also included in this family of reports are the following reports, which are not being revised: the Financial Statements of U.S. Nonbank Subsidiaries Held by Foreign Banking Organizations (FR Y–7N) and the Abbreviated Financial Statements of U.S. Nonbank Subsidiaries Held by Foreign Banking Organizations (FR Y–7NS).

[2] Total combined assets of the top-tier FBO's U.S. domiciled affiliates should exclude the assets of section 2(h)(2) companies as defined in section 2(h)2 of the Bank Holding Company Act (12 U.S.C. 1841(h)(2)) and DPC branch subsidiaries. This item excludes the assets of U.S. branches and agencies.

[3] 79 FR 17240, 17273 (March 27, 2014).

[4] 12 CFR 252.152(b)(2).

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the

assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 18, 2014.

A. Federal Reserve Bank of St. Louis (Yvonne Sparks, Community Development Officer) P.O. Box 442, St. Louis, Missouri 63166–2034:

1. *First Waterloo Bancshares, Inc.,* Waterloo, Illinois; to acquire 100 percent of the voting shares of Prairie National Bank, Stewardson, Illinois.

Board of Governors of the Federal Reserve System, November 18, 2014.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2014–27603 Filed 11–20–14; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Senior Executive Service Performance Review Board

AGENCY: Federal Retirement Thrift Investment Board.

ACTION: Notice.

SUMMARY: This notice announces the appointment of the members of the Senior Executive Service Performance Review Boards for the Federal Retirement Thrift Investment Board. The purpose of the Performance Review Boards is to make written recommendations on annual summary ratings to the appointing authority on the performance of senior executives.

DATES: This notice is effective November 18, 2014.

FOR FURTHER INFORMATION CONTACT: Kelly Powell, HR Specialist, at 202–942–1681.

SUPPLEMENTARY INFORMATION: Title 5, U.S. Code, 4314(c)(4), requires that the appointment of Performance Review Board members be published in the **Federal Register** before Board service commences. The following persons will serve on the Federal Retirement Thrift Investment Board's Performance Review Boards which will review initial summary ratings to ensure the ratings are consistent with established performance requirements, reflect meaningful distinctions among senior executives based on their relative performance and organizational results and provide recommendations for ratings, awards, and pay adjustments in a fair and equitable manner: Jay Ahuja, Jim Courtney, Susan Crowder, Thomas Emswiler, Tracey Ray, Renee Wilder.

Megan Grumbine,

Deputy General Counsel, Federal Retirement Thrift Investment Board.

[FR Doc. 2014–27607 Filed 11–20–14; 8:45 am]

BILLING CODE 6760–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–15–0572]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public 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. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404–639–7570 or send comments to Leroy A. Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov*.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

Health Message Testing System (HMTS) (OMB No. 0920–0572, expires 02/28/2015)—Extension—Office of the Associate Director for Communication (OADC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Before CDC disseminates a health message to the public, the message always undergoes scientific review. However, even though the message is based on sound scientific content, there is no guarantee that the public will understand a health message or that the message will move people to take recommended action. Communication theorists and researchers agree that for health messages to be as clear and influential as possible, target audience members or representatives must be involved in developing the messages and provisional versions of the messages must be tested with members of the target audience.

However, increasingly there are circumstances when CDC must move swiftly to protect life, prevent disease, or calm public anxiety. Health message testing is even more important in these instances, because of the critical nature of the information need.

In the interest of timely health message dissemination, many programs forgo the important step of testing

messages on dimensions such as clarity, salience, appeal, and persuasiveness (i.e., the ability to influence behavioral intention). Skipping this step avoids the delay involved in the standard OMB review process, but at a high potential cost. Untested messages can waste communication resources and opportunities because the messages can be perceived as unclear or irrelevant. Untested messages can also have unintended consequences, such as jeopardizing the credibility of Federal health officials.

The Health Message Testing System (HMTS), a generic information collection, enables programs across CDC to collect the information they require in a timely manner to:

- Ensure quality and prevent waste in the dissemination of health information by CDC to the public.
- Refine message concepts and to test draft materials for clarity, salience, appeal, and persuasiveness to target audiences.
- Guide the action of health communication officials who are responding to health emergencies, Congressionally-mandated campaigns with short timeframes, media-generated public concern, time-limited communication opportunities, trends, and the need to refresh materials or dissemination strategies in an ongoing campaign.

Each testing instrument will be based on specific health issues or topics. Although it is not possible to develop one instrument for use in all instances, the same kinds of questions are asked in most message testing. This package includes generic questions and formats that can used to develop health message testing data collection instruments. These include a list of screening questions, comprised of demographic and introductory questions, along with other questions that can be used to create a mix of relevant questions for each proposed message testing data collection method. However, programs may request to use additional questions if needed.

Message testing questions will focus on issues such as comprehension, impressions, personal relevance, content and wording, efficacy of response, channels, and spokesperson/sponsor. Such information will enable message developers to enhance the effectiveness of messages for intended audiences.

Data collection methods proposed for HMTS includes intercept interviews, telephone interviews, focus groups, online surveys, and cognitive interviews. In almost all instances, data will be collected by outside organizations under contract with CDC.

For many years CDC programs have used HMTS to test and refine message concepts and test draft materials for clarity, salience, appeal, and persuasiveness to target audiences. Having this generic clearance available has enabled them to test their information and get critical health information out to the public quickly. Over the last three years, more than 20 messages have been tested using this clearance. For example: *Evaluation of Emergency Preparedness Materials for Limited English Proficient Spanish Speakers.* Risk communication is a top priority in CDC's anthrax preparedness activities. The Anthrax Management Team developed materials to provide LEP Spanish-speakers with information needed to increase the chances for survival in the event that bioterrorists attacked the U.S. using anthrax. Once refined, based on participant feedback, these materials will be used in creating additional public education materials to be utilized during an anthrax emergency. The lessons learned about communication with vulnerable populations have application to others who are seeking to improve communication during a domestic or global public health emergency.

The Division of Diabetes Translation obtained OMB approval through HMTS for *Testing of Brand Concepts, Messages and Materials* for CDC's National Diabetes Prevention Program (National DPP). Materials testing was conducted with multiple audiences, and provided the detailed level of feedback needed to make materials that resonate with each audience. Findings have also been used to inform the development and testing of a new brand for the National DPP which will be launched in 2015.

The National Institute for Occupational Safety and Health (NIOSH) conducted a field study, *Spanish Trench Safety CD–ROM,* to determine the most effective way to disseminate trench safety information to Latino immigrant workers using computer-based training. Using results of this study, NIOSH produced the CD–ROM and are preparing to field test the product. As part of this project, a tutorial was also created for workers with limited computer literacy teaching them how to use the computer. The tutorial has been field tested and the English and Spanish versions will become NIOSH numbered publications.

Over 12,000 respondents were queried and over 5,500 burden hours used during this time period. Because the availability of this information collection has been so critical to programs in disseminating their materials and information to the public in a timely manner, OADC is requesting a three year extension of this information collection.

There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent (examples)	Form name (examples)	Number of respondents	Number of responses per respondent	Avg. burden per response	Total burden in hours
Public Health Professionals, Health Care Providers, State and Local Public Health Officials, Emergency Responders, General Public.	Moderator's Guides, Eligibility Screeners, Interview Guides, Opinion Surveys, Consent Forms.	18,525	1	8/60	2,470
Total					2,470

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. 2014–27619 Filed 11–20–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10291, CMS–10114, and CMS–10392]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *December 22, 2014.*

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 or Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* State Collection and Reporting of Dental Provider and Benefit Package Information on the Insure Kids Now! Web site and Hotline; *Use:* On the Insure Kids Now (IKN) Web site, the Secretary is required to post a current and accurate list of dentists and providers that provide dental services to children enrolled in the state plan (or waiver) under Medicaid or the state child health plan (or waiver) under CHIP. States collect the information pertaining to their Medicaid and CHIP dental benefits. *Form Number:* CMS–10291 (OMB control number: 0938–1065); *Frequency:* Yearly and quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 255; *Total Annual Hours:* 10,838. (For policy questions regarding this collection contact Laurie Norris at 410–786–6543.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* National Provider Identifier (NPI) Application and Update Form and Supporting Regulations in 45 CFR 142.408, 45 CFR 162.406, 45 CFR 162.408; *Use:* The National Provider Identifier (NPI) Application and Update Form is used by health care providers to apply for NPIs and furnish updates to the information they supplied on their initial applications. The form is also used to deactivate their NPIs if necessary. The NPI Application/Update form has been revised to provide additional guidance on how to accurately complete the form. The NPI Application/Update form has been revised to provide additional guidance on how to accurately complete the form. This collection includes clarification on information that is required on applications/changes. Minor changes on the application/update form include adding a 'Subpart' check box in the Other Name section and a revision within the PRA Disclosure Statement. This collection also includes changes to the instructions. *Form Number:* CMS–10114 (OMB control number: 0938–0931); *Frequency:* Reporting—On occasion; *Affected Public:* Business or other for-profit, not-for-profit institutions, and Federal government; *Number of Respondents:* 608,880; *Total Annual Responses:* 608,880; *Total Annual Hours:* 112,660. (For policy questions regarding this collection contact Kimberly McPhillips at 410–786–5374.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Consumer Operated and Oriented (CO-OP) Program; *Use:* The Consumer Operated and Oriented Plan (CO-OP) program was established by Section 1322 of the Affordable Care Act. This program provides for loans to establish at least one consumer-operated, qualified nonprofit health insurance issuer in each State. Issuers supported by the CO-OP program will offer at least one qualified health plan at the silver level of benefits and one at the gold level of benefits in the individual market State Health Benefit Exchanges (Exchanges). At least two-thirds of policies or contracts offered by a CO-OP will be open to individuals and small employers. Profits generated by the nonprofit CO-OPs will be used to lower premiums, improve benefits, improve the quality of health care delivered to their members, expand enrollment, or

otherwise contribute to the stability of coverage offered by the CO-OP. By increasing competition in the health insurance market and operating with a strong consumer focus, the CO-OP program will provide consumers more choices, greater plan accountability, increased competition to lower prices, and better models of care, benefiting all consumers, not just CO-OP members.

The CO-OP program will provide nonprofits with loans to fund start-up costs and State reserve requirements, in the form of Start-up Loans and Solvency Loans. An applicant may apply for (1) Joint Start-up and Solvency Loans; or (3) only a Solvency Loan. Planning Loans are intended to help loan recipients determine the feasibility of operating a CO-OP in a target market. Start-up Loans are intended to assist loan recipients with the many start-up costs associated with establishing a new health insurance issuer. Solvency Loans are intended to assist loan recipients with meeting the solvency requirements of States in which the applicant seeks to be licensed to issue qualified health plans. *Form Number:* CMS–10392 (OMB control number: 0938–1139); *Frequency:* Occasionally; *Affected Public:* Private sector—not-for-profit institutions; *Number of Respondents:* 23; *Total Annual Responses:* 583; *Total Annual Hours:* 11,621. (For policy questions regarding this collection contact Deepti Loharikar (301–492–4126.)

Dated: November 18, 2014.

Martique Jones,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–27640 Filed 11–20–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3305–PN]

Medicare and Medicaid Programs: Application From the American Association for Accreditation of Ambulatory Surgery Facilities for Continued Approval of Its Accreditation Program for Organizations That Provide Outpatient Physical Therapy and Speech Language Pathology Services

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice acknowledges the receipt of an application from the American Association for Accreditation of Ambulatory Surgery Facilities for continued recognition as a national accrediting organization for organizations that provide outpatient physical therapy and speech language pathology services that wish to participate in the Medicare or Medicaid programs. The statute requires that within 60 days of receipt of an organization's complete application, we publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 22, 2014.

ADDRESSES: In commenting, refer to file code CMS–3305–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3305–PN, P.O. Box 8016, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3305–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written only to the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Cindy Melanson, (410) 786–0310. Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from an outpatient physical therapy and speech language pathology service (OPT) provided certain requirements are met. Section 1861(p) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as an OPT. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations

at 42 CFR part 485, subpart H specify the minimum conditions that an OPT must meet to participate in the Medicare program.

Generally, to enter into an agreement, an OPT must first be certified by a state survey agency as complying with the conditions or requirements set forth in part 485, subpart H of our Medicare regulations. Thereafter, the OPT is subject to regular surveys by a state survey agency to determine whether it continues to meet these requirements. There is an alternative, however, to surveys by state agencies.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a CMS-approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we may deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary of the Department of Health and Human Services (the Secretary) as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. A national accrediting organization applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require accrediting organizations to reapply for continued approval of its accreditation program every 6 years or sooner as determined by CMS.

The American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF's) current term of approval for their OPT accreditation program expires April 22, 2015.

II. Approval of Deeming Organizations

Section 1865(a)(2) of the Act and our regulations at § 488.8(a) require that our findings concerning review and approval of a national accrediting organization's requirements consider, among other factors, the applying accrediting organization's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of AAAASF's request for continued approval of its OPT accreditation program. This notice also solicits public comment on whether AAAASF's requirements meet or exceed the Medicare conditions of participation (CoPs) for OPTs.

III. Evaluation of Deeming Authority Request

AAAASF submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its OPT accreditation program. This application was determined to be complete on September 29, 2014. Under Section 1865(a)(2) of the Act and our regulations at § 488.8 (Federal review of accrediting organizations), our review and evaluation of AAAASF will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of AAAASF's standards for OPTs as compared with Medicare's OPT CoPs.
- AAAASF's survey process to determine the following:

—The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

—The comparability of AAAASF's processes to those of state agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

—AAAASF's processes and procedures for monitoring a OPT found out of compliance with AAAASF's program requirements. These monitoring procedures are used only when AAAASF identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the state survey agency monitors corrections as specified at § 488.7(d).

—AAAASF's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

—AAAASF's capacity to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

—The adequacy of AAAASF's staff and other resources, and its financial viability.

—AAAASF's capacity to adequately fund required surveys.

—AAAASF's policies to assure that surveys are unannounced.

—AAAASF's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey that CMS may request (including corrective action plans).

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

V. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Dated: November 5, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–27649 Filed 11–20–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3301–FN]

Medicare and Medicaid Programs; Continued Approval of DNV GL—Healthcare (DNV GL) Critical Access Hospital (CAH) Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve DNV GL—Healthcare (DNV GL) [1] for continued recognition as a national accrediting organization (AO) for critical access hospitals (CAH) that wish to participate in the Medicare or Medicaid programs.

DATES: This final notice is effective December 23, 2014 through December 23, 2020.

FOR FURTHER INFORMATION CONTACT: Barbara Easterling, (410) 786–0482, Lillian Williams, 410–786–8636, Cindy Melanson, (410) 786–0310, or Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a Critical Access Hospital (CAH) provided certain requirements are met. Sections 1820(c)(2)B, 1820(e) and 1861(mm)(1) of the Social Security Act (the Act) establish distinct criteria for facilities seeking designation as a CAH. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 485, subpart F, specify the conditions that a CAH must meet to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for CAHs.

Generally, to enter into an agreement, a CAH must first be certified by a state survey agency as complying with the conditions or requirements set forth in part 485, subpart F. Thereafter, the CAH is subject to regular surveys by a state survey agency to determine whether it continues to meet these requirements. However, there is an alternative to surveys by state agencies. Certification by a nationally recognized accreditation program can substitute for ongoing state review.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary of the Department of Health and Human Services as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. A national AO applying for approval of its accreditation program under part 488, subpart A, must provide us with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions.

Our regulations concerning the approval of AOs are set forth at § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require an AO to reapply for continued approval of its accreditation program every 6 years or sooner as determined by us. The DNV GL's current term of approval for their CAH accreditation program expires December 23, 2014.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS-approval of an accreditation program is conducted in a timely manner. The Act provides us with 210 calendar days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

On June 27, 2014, we published a proposed notice in the **Federal Register** (79 FR 36521) announcing DNV GL's request for approval of its CAH accreditation program. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.4 and § 488.8, we conducted a review of DNV GL's application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of DNV GL's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and, (5) survey review and decision-making process for accreditation.
- The comparison of DNV GL's accreditation to our current Medicare CAH conditions of participation (CoPs).
- A documentation review of DNV GL's survey process to:

++ Determine the composition of the survey team, surveyor qualifications, and DNV GL's ability to provide continuing surveyor training.

++ Compare DNV GL's processes to those of state survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ Evaluate DNV GL's procedures for monitoring CAHs out of compliance with DNV GL's program requirements. The monitoring procedures are used only when DNV GL identifies noncompliance. If noncompliance is identified through validation reviews, the state survey agency monitors corrections as specified at § 488.7(d).

++ Assess DNV GL's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ Establish DNV GL's ability to provide us with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ Determine the adequacy of staff and other resources.

++ Confirm DNV GL's ability to provide adequate funding for performing required surveys.

++ Confirm DNV GL's policies with respect to whether surveys are announced or unannounced.

++ Obtain DNV GL's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the June 27, 2014 proposed notice also solicited public comments regarding whether DNV GL's requirements met or exceeded the Medicare conditions of participation for CAHs. We received no comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between DNV GL's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements

We compared DNV GL's CAH requirements and survey process with the Medicare conditions of participation and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of DNV GL's

[1] Formerly known as Det Norske Veritas Healthcare, Inc. (DNVHC).

CAH accreditation program application, which were conducted as described in section III of this final notice, yielded the following:

- To meet the requirements at § 412.25(d), DNV GL revised its standards to address the number of excluded units permitted.
- To meet the requirements at § 412.27(c)(2)(vii), DNV GL revised its standards to include the requirement for an inventory of the inpatient's assets in a descriptive fashion and ensured that consistent language is used in the crosswalk and manual.
- To meet the requirements at § 412.27(d)(3), DNV GL revised its standards to more fully address nursing services requirements.
- To meet the requirements § 412.27(d)(4), DNV GL revised its standards to address ''service objectives'' for psychological services.
- To meet the requirements at § 412.27(d)(6)(ii), DNV GL revised its standards to address the number of ''qualified therapists, support personnel and consultants'' needed to provide comprehensive therapeutic activities consistent with each inpatient's active treatment program.
- To meet the requirements at § 412.29(h), DNV GL revised its standards to ensure a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.
- To meet the requirements at § 482.12(c)(1)(iv), DNV GL revised its standards related to a doctor of optometry.
- To meet the requirements at § 482.12(c)(2), DNV GL revised its standards to address the regulatory language, ''patients are admitted to the hospital only on the recommendation of a licensed practitioner.''
- To meet the requirements at § 482.13(h)(1), DNV GL revised its standards to more fully address the requirement to inform each patient (or ''support person, where appropriate'') of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her rights under this section, and ensured consistent language is used in its manual and crosswalk.
- To meet the requirements at § 482.21(e)(1), DNV GL revised its standards to ensure that an ongoing quality assurance performance improvement program is ''maintained.''
- To meet the requirements at § 482.22(c)(5)(i) through (ii), DNV GL revised its standards to ensure that a medical history and physical is conducted, completed, and updated in accordance with ''hospital policy.''
- To meet the requirements at § 482.25(b)(2)(i), DNV GL revised its crosswalk to address the requirement that all drugs and biologicals must be kept in a secure area, and locked when appropriate.
- To meet the requirements at § 482.27(b)(3)(i), DNV GL revised its standards to more fully address the regulatory language related to HIV testing of blood and blood components from a blood donor who tested negative at the time of donation, but tests reactive for evidence of HIV or HCV infection on a later donation, ''or who is at increased risk for transmitting HIV or HCV infection.''
- To meet the requirements at § 482.30(f), DNV GL revised its crosswalk to address review of professional services.
- To meet the requirements at § 482.41(b)(6), DNV GL revised its standards to include a requirement for the proper routine storage and prompt disposal of all trash.
- To meet the requirements at § 482.41(b)(7), DNV GL revised its standards to address the evacuation and relocation plan requirement, periodic instruction for employees and a readily available plan in the telephone operator's position at the security center.
- To meet the requirements at § 483.12(a)(8), DNV GL revised its standards to address written advance notice of facility closure.
- To meet the requirements at § 483.15(f)(2)(i), DNV GL revised its standards to address this requirement for a qualified therapeutic recreational specialist or an activities professional.
- To meet the requirements at § 483.15(f)(2)(i), DNV GL revised its standards to include standards requiring a qualified therapeutic recreation specialist.
- To meet the requirements at § 483.55(a)(1), DNV GL revised its standards to address the requirement that the facility provide or obtain from an outside resource, routine and emergency dental services to meet the needs of each resident.
- To meet the requirements at § 485.604(c)(3), DNV GL revised its standards to include the requirement that physician assistants must have been assisting primary care physicians for a total of 12 months during the 18-month period immediately preceding June 25, 1993.
- To meet the requirements at § 485.604(b)(3), DNV GL revised its standards and crosswalk to address the requirement that the nurse practitioner must have ''been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding June 25, 1993.''
- To meet the requirements at § 485.604(c)(2)(ii), DNV GL revised its standards to more fully address physician assistant supervised clinical practice and classroom instruction program requirements.
- To meet the requirements at § 485.606, DNV GL revised its referenced standard and crosswalk to address how DNV GL determines that the appropriate CAH designations and certifications have been made by CMS and/or the state agency.
- To meet the requirements at § 485.608, DNV GL revised its standards to include compliance with federal, state and local CAH laws and regulations and to reconcile the inconsistent language between the manual and crosswalk.
- To meet the requirements at § 485.608(a), DNV GL revised its standards to address the requirement that the CAH must be licensed in accordance with federal ''regulations.''
- To meet the requirements at § 485.608(b), DNV GL revised its standards and crosswalk to address the requirement that all patient services are furnished in accordance with applicable ''local'' laws, and to address furnishing patient care services in accordance with state and local ''regulations.''
- To meet the requirements at § 485.608(c), DNV GL revised its standards to address the requirement that the CAH is licensed in accordance with applicable federal, state, and local ''regulations.''
- To meet the requirements at § 485.608(d), DNV GL revised its standards to address the requirement that staff of the CAH are ''licensed, certified, or registered in accordance with applicable federal, state, and local regulations.''
- To meet the requirements at § 485.612, DNV GL revised its standards to ensure the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.
- To meet the requirements at § 485.616(a), DNV GL revised its standards and crosswalk to address agreements with network hospitals.
- To meet the requirements at § 485.616(b), DNV GL revised its standards and crosswalk to address agreements for credentialing and quality assurance.
- To meet the requirements at § 485.616(c) through (c)(1)(ii), DNV GL

revised its standards to address agreements for credentialing and privileging of telemedicine physicians and practitioners.

- To meet the requirements at § 485.616(c)(2)(iv), DNV GL updated their Medicare cross-walk to include standards to address when telemedicine services are provided to the CAH's patients through an agreement with a distant site hospital, the CAH's governing body or responsible individual may choose to rely upon the credentialing and privileging decisions of the distant site hospital.
- To meet the requirements at § 485.616(c)(3), DNV GL revised its standards to address the governing body of the CAH must ensure that telemedicine services are furnished in accordance with § 485.635(c)(4)(ii) and to ensure consistent language in its crosswalk.
- To meet the requirements at § 485.618(c), DNV GL revised its standards to address the requirement that the facility provide blood and blood products, either directly or under arrangement.
- To meet the requirements at § 485.618(c)(1), DNV GL revised its standards to address the requirement that the facility provide services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hour a day basis.
- To meet the requirements at § 485.618(c)(2), DNV GL revised its standards and crosswalk to address blood storage facilities.
- To meet the requirements at § 485.618(d)(1), DNV GL revised its standards to address personnel requirements and to ensure consistent language in its crosswalk.
- To meet the requirements at § 485.623, DNV GL revised its standards to address physical plant and environment and to ensure consistent language in its crosswalk.
- To meet the requirements at § 485.631(b)(1)(ii), DNV GL revised its standards to address written policies governing services the CAH furnishes.
- To meet the requirements at § 485.631(b)(1)(iii), DNV GL revised its standards to address the requirement for providing medical orders.
- To meet the requirements at § 485.631(b)(2), DNV GL revised its standards to address the requirement for providing medical care services.
- To meet the requirements at § 485.631(c)(1)(i), DNV GL revised its standards to address other CAH non-clinical written policies.
- To meet the requirements at § 485.635(a)(3)(ii), DNV GL revised its standards to address the requirement for emergency medical services policies and procedures.
- To meet the requirements at § 485.635(a)(3)(iii), DNV GL revised its standards to address ''the maintenance of health care records.''
- To meet the requirements at § 485.635(a)(3)(iv), DNV GL revised its standards to address the requirement that current and accurate records are kept of the receipt and disposition of all scheduled drugs.
- To meet the requirements at § 485.635(b)(1)(ii), DNV GL revised its standards to clarify how their surveyors determine that a CAH furnishes acute care inpatient services when no inpatients are present at the time of the survey.
- To meet the requirements at § 485.635(d)(1), DNV GL revised its standards to clarify under what authority nursing services may be provided or supervised by a Physician Assistant (PA) where permitted by state law.
- To meet the requirements at § 485.635(d)(4), DNV GL revised its standards and crosswalk to fully address the requirement that a nursing care plan must be developed and kept current for each patient.
- To meet the requirements at § 485.638(a)(4), DNV GL revised its standards to more fully address the requirement that the CAH maintains a medical record for each patient receiving health care services.
- To meet the requirements at § 485.638(a)(4)(iii), DNV GL revised its standards to fully address the requirement that the medical record contains ''reports of treatments and medications.''
- To meet the requirements at § 485.639(a), DNV GL revised its standards to fully address the requirement related to designation of qualified practitioners allowed to perform surgery ''in accordance with approved policies and procedures, and with state scope of practice laws.''
- To meet the requirements at § 485.639(b)(2) and (b)(3), DNV GL revised its standards to address the requirement to specify a ''qualified'' practitioner examine each patient before surgery to evaluate the risk of anesthesia.
- To meet the requirements at § 485.641(b)(5)(i), DNV GL revised its standards to fully address the requirement that the CAH consider the findings of the evaluations, ''including any findings or recommendations of the Quality Improvement Organization (QIO),'' and takes corrective action if necessary.
- To meet the requirements at § 485.645, DNV GL revised its standards to explain how it would determine that we have granted approval for the CAH to provide and be paid for post-hospital SNF level care as specified in 42 CFR 409.30.
- To meet the requirements § 488.28(a) and section 2728B of the State Operations Manual (SOM), DNV GL amended its policies to ensure that the accepted PoCs contains the elements comparable to those specified in the SOM, section 2728B.
- To meet the requirements at § 488.6, DNV GL provided a written plan to address the components of the CAH application for Distinct Part Units (DPUs) and swing beds, and to ensure that the surveys consistently document evaluation of the CAH's DPUs and swing beds, as applicable.
- To meet the requirements at § 488.8(a)(2)(iv), DNV GL developed an action plan designed to: Strengthen DNV GL surveyor documentation skills; consistently develop more detailed, quantifiable deficiency statements that contain all evidence collected by the survey team; and support the determination of the manner and degree of non-compliance and the appropriate level of citation.
- To meet the requirements at § 489.13(b), DNV GL revised its policy for determining the effective date of accreditation for an initial and re-accreditation survey.

B. Term of Approval

Based on our review and observations described in section IV of this final notice, we have determined that DNV GL's CAH accreditation program requirements meet or exceed our requirements. Therefore, we approve DNV GL as a national accreditation organization for CAHs that request participation in the Medicare program, effective December 23, 2014 through December 23, 2020.

V. Collection of Information Requirements

This document does not impose information collection, recordkeeping requirements or third party disclosure requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Dated: November 13, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–27576 Filed 11–20–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3297–FN]

Medicare and Medicaid Programs: Continued Approval of The Joint Commission's Ambulatory Surgical Center Accreditation Program

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This final notice announces our decision to approve The Joint Commission (TJC) for continued recognition as a national accrediting organization for ambulatory surgical centers (ASCs) that wish to participate in the Medicare or Medicaid programs.

DATES: This final notice is effective December 20, 2014 through December 20, 2020.

FOR FURTHER INFORMATION CONTACT: Monda Shaver (410) 786–3410, Cindy Melanson, (410) 786–0310, or Patricia Chmielewski, (410) 786–6899.

SUPPLEMENTARY INFORMATION:

I. Background

A healthcare provider may enter into an agreement with Medicare to participate in the program as an Ambulatory Surgical Center (ASC) provided certain requirements are met. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) establishes criteria for providers seeking participation as an ASC. Regulations concerning Medicare provider agreements in general are at 42 CFR part 489 and those pertaining to the survey and certification for Medicare participation of providers and certain types of suppliers are at 42 CFR part 488. The regulations at 42 CFR part 416 specify the specific conditions that a provider must meet to participate in the Medicare program as an ASC.

Generally, to enter into a Medicare provider agreement, a facility must first be certified as complying with the conditions set forth in part 416 and recommended to CMS for participation by a State survey agency. Thereafter, the ASC is subject to periodic surveys by a State survey agency to determine whether it continues to meet these conditions. Accreditation by a nationally recognized Medicare accreditation program approved by CMS may substitute for both initial and ongoing State review.

Section 1865(a)(1) of the Act provides that, if the Secretary of the Department of Health and Human Services (the Secretary) finds that accreditation of a provider entity by an approved national accrediting organization meets or exceeds all applicable Medicare conditions, we may treat the provider entity as having met those conditions, that is, we may ''deem'' the provider entity to be in compliance. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

Part 488, subpart A, implements the provisions of section 1865 of the Act and requires that a national accrediting organization applying for approval of its Medicare accreditation program must provide us with reasonable assurance that the accrediting organization requires its accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at § 488.4 and § 488.8(d)(3). The regulations at § 488.8(d)(3) require an accrediting organization to reapply for continued approval of its Medicare accreditation program every 6 years or sooner as as determined by CMS. The Joint Commission (TJC's) current term of approval as a recognized Medicare accreditation program for ASCs expires December 20, 2014.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS-approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

In the June 27, 2014 **Federal Register** (79 FR 36522), we published a proposed notice announcing TJC's request for continued approval of its Medicare ASC accreditation program. In the June 27, 2014 proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.4 and § 488.8, we conducted a review of TJC's Medicare ASC accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of TJC's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its ASC surveyors; (4) ability to investigate and respond appropriately to complaints against accredited ASCs; and (5) survey review and decision-making process for accreditation.
- The comparison of TJC's Medicare accreditation program standards to our current Medicare ASC conditions for coverage (CfCs).
- A documentation review of TJC's survey process to—

++ Determine the composition of the survey team, surveyor qualifications, and TJC's ability to provide continuing surveyor training.

++ Compare TJC's processes to those CMS require of State survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited ASCs.

++ Evaluate TJC's procedures for monitoring ASCs found to be out of compliance with TJC's program requirements. (This pertains only to monitoring procedures when TJC identifies non-compliance. If noncompliance is identified by a State survey agency through a validation survey, the State survey agency monitors corrections as specified at § 488.7(d).)

++ Assess TJC's ability to report deficiencies to the surveyed ASCs and respond to the ASC's plan of correction in a timely manner.

++ Establish TJC's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ Determine the adequacy of TJC's staff and other resources.

++ Confirm TJC's ability to provide adequate funding for performing required surveys.

++ Confirm TJC's policies with respect to surveys being unannounced.

++ Obtain TJC's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey

as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the June 27, 2014 proposed notice also solicited public comments regarding whether TJC's requirements met or exceeded the Medicare CfCs for ASCs. We received no comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between TJC's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared TJC's ASC accreditation requirements and survey process with the Medicare CfCs of part 416, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of TJC's ASC application was conducted as described in section III of this final notice. As of the date of this notice, TJC is in the process of or has completed revising its standards and certification processes in order to meet the following requirements:

- Section 416.41, to address the ASC's Governing Body's responsibility for oversight and accountability for determining, implementing, and monitoring policies governing the ASC's total operation.
- Section 416.41(b)(1), to ensure the ASC is required to have an effective procedure for the immediate transfer to a hospital and patients requiring emergency medical care beyond the capabilities of the ASC.
- Section 416.41(b)(2), to address the requirement that the hospital be a local, Medicare-participating hospital or a local, nonparticipating hospital that meets the requirements for payment for emergency services under § 482.2.
- Section 416.41(b)(3)(i), to ensure the ASC has a written transfer agreement with a hospital that meets the requirements at § 416.41(b)(2).
- Section 416.41(b)(3)(ii), to address the requirement that all physicians performing surgery in the ASC have admitting privileges at a hospital that meets the requirements at § 416.41(b)(2).
- Section 416.42(c)(1) and § 416.42(c)(2), to address State exemption from the requirement for physician supervision of a certified registered nurse anesthetist.
- Section 416.43(a)(1), to address the requirement that the program demonstrate measurable improvements in health outcomes and improves patient safety by the identification and reduction of medical errors.
- Section 416.43(c)(1)(ii), to address requirements related to the setting of priorities for ASC performance improvement activities.
- Section 416.43(e)(1), to ensure the Governing Body takes responsibility and is involved in the operation of the ASCs [Quality Assessment Performance Improvement (QAPI) Program.
- Section 416.43(e)(2), to include the requirement that the Governing Body is responsible for addressing the ASC's priorities and that all improvements are evaluated for effectiveness.
- Section 416.43(e)(4), to ensure that the ASC clearly establishes its expectations for safety.
- Section 416.44(a), to ensure ASCs maintain equipment in accordance with manufacturer requirements or other Federal or State requirements.
- Section 416.44(a)(1), to ensure operating rooms are designed and equipped so that the types of surgery conducted can be performed in a manner that protects the lives and assures the physical safety of all individuals in the area.
- Section 416.44(b)(1), to include the provisions required under the 2000 edition of the Life Safety Code of the National Fire Protection Association.
- Section 416.44(b)(2), to address requirements related to life safety code waivers.
- Section 416.44(c), to address the requirement that the ASC medical staff and governing body coordinate, develop and revise ASC policies and procedures to specify the types of emergency equipment required for use in the ASC's operating room.
- Section 416.45(c), to include a provision that should the ASC assigns patient care responsibilities to practitioners other than physicians, it must have established policies and procedures approved by the governing body for overseeing and evaluating their clinical activities.
- Section 416.47(b), to address the timeframe within which the pre-operative diagnostic studies must be present in the medical record.
- Section 416.48(a), to address the preparation of drugs.
- Section 416.49(a), to include the requirement that the ASC must have procedures for obtaining routine and emergency laboratory services from a certified laboratory when the ASC does not provide its own laboratory services.
- Section 416.49(b)(2), to include the requirement that radiologic services must meet the hospital conditions of participation for radiologic services specified in § 482.26.
- Section 416.50, to update the Medicare regulatory language on its standards crosswalk.
- Section 416.50(c)(3), to address the requirement that the ASC document in a prominent part of the medical record whether or not the individual has executed an advance directive.
- Section 416.50(g), to ensure the ASC complies with the Department of Health and Human Services (the Department) rules for the privacy and security of individually identifiable health information
- Section 416.51(a), to ensure the ASC provides a functional and sanitary environment for the provision of surgical services by adhering to professionally acceptable standards of practice.
- Section 416.51(b), to address the requirement that the ASC infection control and prevention program include documentation that the ASC has considered, selected, and implemented nationally recognized infection control program guidelines.
- Section 416.52(b)(1), to address the requirement related to whom may document that the patient has met discharge criteria.
- Section 416.52(c)(2), to address the requirement that each patient has a discharge order signed by the physician who performed the surgery or procedure in accordance with applicable State health and safety laws, standards of practice, and ASC policy.
- Section 488.4(a)(4), to clarify the minimum composition of its survey team for its Medicare ASC accreditation program.
- Section 488.4(a)(4)(ii) through (v), to ensure compliance with its own policies that require evidence that its surveyors are appropriately qualified, trained, and evaluated.
- Section 488.4(a)(6), to ensure compliance with its own policies that require requests for a plan of correction (PoC) be timely, follow-up surveys for immediate threat to life (ITL) situations to be conducted timely, and that findings are accurately reported to CMS via the Accrediting Organization System for Storing User Recorded Experiences (ASSURE) database system.
- Section 488.4(b)(3)(iii) and § 488.8(d), to ensure CMS is notified of any proposed changes in its CMS-approved Medicare ASC accreditation program 30 days prior to implementation of such changes, and to confirm that it will not implement changes CMS have disapproved or required to be modified.
- Section 488.8, to provide CMS with data that ensures the following information is accurately reported: the date of a complaint receipt; determination of complaints as substantiated or unsubstantiated;

determinations of ITL situations; and surveyor documentation that includes a detailed deficiency statement that clearly supports the determination of manner and degree of non-compliance and the appropriate level of citation.

• Section 488.8(a)(2)(iv), to strengthen surveyor documentation to include sufficient detail to support the determination of the manner and degree of non-compliance and the appropriate level of deficiency citation.

• Section 489.13, related to the effective date of accreditation for facilities undergoing a survey for purposes of its initial participation in Medicare; to ensure the effective date of accreditation when deficiencies have been identified, and to ensure it is consistent with CMS regulatory requirements.

• To ensure comparability with the survey process requirements at § 488.26(d), TJC must have—

++ Updated its accreditation process policies to clarify that all surveys for TJC's Medicare ASC accreditation program are conducted unannounced.

++ Updated its accreditation process policies to ensure all required follow-up surveys for its Medicare ASC accreditation program meet the Medicare requirements.

++ Revised its accreditation process policies to clarify that the appropriate level of citation be made when an Immediate Threat to Health or Safety is identified.

++ Clarified its survey policies in the surveyor activity guide (SAG) to address how ''Special Issue Resolution'' is handled during surveys lasting only 1 day.

++ Updated its ASC accreditation process policies to clearly demonstrate that the policies are related to ASCs and not hospitals.

• Section 488.28(a), to include all documented observations of non-compliance and all internal, uncompleted Plans for Improvement (PFI) listed in the accredited ASC's ''Statement of Condition (SOC) to correct Life Safety Code Deficiencies'' into the survey report. In addition, TJC will provide CMS with rationale for each standard for which TJC has determined will not require a citation of non-compliance when a single observation has been made.

• Complied with section 1861(e)(9)(C) of the Act, to require that waiver and equivalency requests submitted by accredited organizations for Life Safety Code deficiencies that would result in unreasonable hardship for such a facility to resolve and would not jeopardize patient health or safety, be reviewed by TJC, and forwarded to CMS for approval, as appropriate.

• To demonstrate comparability with minimum eligibility requirements for Initial surveys, increased the minimum number of patients/volume of services from three patients served with one active at the time of survey, to ten patients served, with one active at the time of survey.

• To comply with TJS's own policies, TJS must—

++ Ensure its surveyors complete the ASC Infection Control Worksheet on every survey.

++ Ensure its surveyors observe at least one surgery during every survey.

++ Ensure that the minimum number of medical records have been reviewed on every survey.

++ Ensure that findings noted on the Infection Control Worksheet are integrated into the survey report findings.

B. Term of Approval

Based on our review and observations described in section III of this final notice, we approve TJC as a national accreditation organization for ASCs that request participation in the Medicare program, effective December 20, 2014 through December 20, 2020.

To verify TJC's continued compliance with the provisions of this final notice, we will conduct a follow-up corporate on-site visit and survey observation within 18 months of the date of publication of this final notice.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Dated: November 5, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–27577 Filed 11–20–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6064–N]

Medicare Program; Prior Authorization of Non-Emergent Hyperbaric Oxygen (HBO) Therapy

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a 3-year Medicare Prior Authorization model for non-emergent hyperbaric oxygen therapy services in the states of Illinois, Michigan, and New Jersey where there have been high incidences of improper payments for these services.

DATES: The model will begin on March 1, 2015 in Michigan, New Jersey, and Illinois.

FOR FURTHER INFORMATION CONTACT: Jennifer McMullen, (410) 786–7635.

Questions regarding the Medicare Prior Authorization Model for Non-Emergent Hyperbaric Oxygen (HBO) Therapy should be sent to *HBOPA@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Hyperbaric Oxygen (HBO) therapy is a modality used for treatment of wounds in which the entire body is exposed to oxygen under increased atmospheric pressure. HBO therapy is covered as adjunctive therapy only after there have been no measurable signs of healing during at least 30 consecutive days of treatment with standard wound therapy, and must be used in addition to standard wound care. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

Medicare issued a National Coverage Determination (NCD) for HBO therapy in 2002, which lists clinical conditions for which HBO therapy is medically necessary and clinical conditions for which HBO therapy is not medically necessary, and therefore; not covered by Medicare. The NCD can be found in the Medicare National Coverage Determinations Manual (CMS Pub. No. 100–03), Chapter 1, Part 1, Section 20.29, and in the NCD database at *http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=37&bc=AiAAAAAAAgAAAA%3d%3d&.* In addition, some of

the Medicare Administrative Contractors (MACs) have Local Coverage Determinations (LCDs) that expand on the NCD.

In 2000, a report by the HHS Office of Inspector General [1] on hyperbaric oxygen therapy found the following:

- $14.2 million (of $49.9 million in allowed charges for outpatient hospital departments and physicians) was paid in error, either for beneficiaries who received treatments for non-covered conditions or when documentation did not adequately support HBO.
- An additional $4.9 million was paid for treatments deemed to be excessive.
- Lack of testing and treatment monitoring raised quality of care concerns.

Data from CMS' Chronic Condition Warehouse were used to determine state rankings based on average number of sessions per beneficiary. States were then ranked by expenditures. Illinois, Michigan, and New Jersey were selected as the initial states for the model because they ranked in the top three for average number of sessions per beneficiary.

Section 1115A of the Social Security Act (the Act) authorizes the Secretary to test innovative payment and service delivery models to reduce program expenditures, while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries.

Section 1115A(d)(1) of the Act authorizes the Secretary to waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) of the Act as may be necessary solely for purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. For this model, consistent with this standard, we will waive such provisions of sections 1834(a)(15) and 1869(h) of the Act that limit our ability to conduct prior authorization. We have determined that the implementation of this model does not require the waiver of any fraud and abuse law, including sections 1128A, 1128B, and 1877 of the Act. Thus, providers and suppliers affected by this model must comply with all applicable fraud and abuse laws. While these provisions are specific to durable medical equipment (DME) and physician services, we will waive any portion of these sections as well as any portion of 42 CFR 410.20(d) of the regulations, which implements section 1869(h) of the Act, that could be construed to limit our ability to conduct prior authorization.

[1] Office of Inspector General, Hyperbaric Oxygen Therapy, Its Use and Appropriateness, October 2000.

II. Provisions of the Notice

We plan to implement a 3-year Medicare Prior Authorization process for non-emergent HBO therapy rendered in 3 states (Illinois, Michigan, and New Jersey). These states were selected as the initial states for the model because of their high utilization and improper payment rates for this service. The model will begin in Michigan, New Jersey, and Illinois on March 1, 2015.

We plan to test whether prior authorization helps reduce expenditures, while maintaining or improving quality of care, using a model that would establish a prior authorization process for non-emergent HBO therapy to reduce utilization of services that do not comply with Medicare policy.

We plan to use this prior authorization process to ensure that all relevant clinical or medical documentation requirements are met before services are rendered to beneficiaries and before claims are submitted for payment. This prior authorization process will further ensure that payment complies with Medicare documentation, coverage, payment, and coding rules.

The use of prior authorization will not create new clinical documentation requirements. Instead, it will require the same information that is already required to support Medicare payment, just earlier in the process. Prior authorization allows facilities to address issues with claims prior to rendering services.

The prior authorization process under this model will be available for the following code for Medicare payment: C1300—Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval.

Prior authorization is only needed for the facility payment part of the HBO therapy service. However, if a facility does not have prior authorization, or has a non-affirmed prior authorization, the associated physician claims with the following code will be subject to medical review: 99183—Physician attendance and supervision of hyperbaric oxygen, per session.

Of the 15 covered clinical conditions listed in the NCD, the following 6 will be available for prior authorization:

- Preparation and preservation of compromised skin grafts (not for primary management of wounds).
- Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management.
- Osteoradionecrosis as an adjunct to conventional treatment.
- Soft tissue radionecrosis as an adjunct to conventional treatment.
- Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment.
- Diabetic wounds of the lower extremities in patients who meet the following three criteria:

++ Patient has Type I or Type II diabetes and a lower extremity wound that is due to diabetes.

++ Patient has a wound classified as Wagner grade III or higher.

++ Patient has failed an adequate course of wound therapy as defined in the NCD.

A provisional affirmative prior authorization decision, justified by the beneficiary's condition, may affirm up to 36 treatments in a 12-month period. A provisional affirmation is a preliminary finding that a future claim submitted to Medicare for the service likely meets Medicare's coverage, coding, and payment requirements. A provisional affirmative decision can be for all or part of the requested number of treatments. If additional treatments are needed, a subsequent prior authorization request must be submitted.

Prior to the start of the model, we will conduct (and thereafter will continue to conduct) outreach and education to facilities that provide HBO therapy, as well as to beneficiaries, through such methods as Open Door Forums, frequently asked questions (FAQs) on our Web site, other Web site postings, and educational materials issued by the Medicare Administrative Contractors (MACs). Additional information about the implementation of the prior authorization model is available on the CMS Web site at *http://go.cms.gov/PAHBO.*

Under this model prior authorization process, the facility or beneficiary will be encouraged to submit to the MAC a request for prior authorization along with all relevant documentation to support Medicare coverage of the HBO therapy. In order to be affirmed, the request for prior authorization must meet all applicable rules and policies, and any NCD and Local Coverage Determination (LCD) requirements for HBO therapy.

After receipt of all relevant documentation, the MACs will make every effort to conduct a review and postmark the notification of their decision on a prior authorization request within 10 business days for an initial submission. Notification will be provided to the submitter of the prior

authorization request (and, upon request, to the beneficiary if he or she was not the original submitter). If a subsequent prior authorization request is submitted after a non-affirmative decision on an initial prior authorization request, the MACs will make every effort to conduct a review and postmark the notification of their decision on the request within 20 business days.

A facility or beneficiary may request an expedited review when the standard timeframe for making a prior authorization decision could jeopardize the life or health of the beneficiary. If the MAC agrees that the standard review timeframe would put the beneficiary at risk, the MAC will make reasonable efforts to communicate a decision within 2 business days of receipt of all applicable, Medicare-required documentation. As this model is for a non-emergent service only, we expect requests for expedited reviews to be extremely rare.

The following describes examples of various prior authorization scenarios:

- Scenario 1: When a facility or beneficiary submits a prior authorization request to the MAC with appropriate documentation and all relevant Medicare coverage and documentation requirements are met for the HBO therapy, the MAC will send a provisional affirmative prior authorization decision to the submitter (and, upon request, to the beneficiary if he or she was not the original submitter). When the claim is submitted to the MAC, it is linked to the prior authorization via the claims processing system and the claim is paid so long as all Medicare coding, billing, and coverage requirements are met. However, after submission, the claim could be denied for technical reasons, such as the claim being a duplicate claim or being for a date of service after a beneficiary's death.
- Scenario 2: When a facility or beneficiary submits a prior authorization request but all relevant Medicare coverage requirements are not met, the MAC will send a non-affirmative prior authorization decision to the submitter (and, upon request, to the beneficiary if he or she was not the original submitter), advising them that Medicare will not pay for the service. The facility or beneficiary may then resubmit the request with documentation showing that Medicare requirements have been met. Alternatively, a facility could render the service, and submit a claim with a non-affirmative prior authorization tracking number, at which point the MAC would deny the claim. The facility or the beneficiary would then have the Medicare denial for secondary insurance purposes and would have the opportunity to submit an appeal of the claim denial if they believe Medicare coverage was denied inappropriately.
- Scenario 3: When a facility or beneficiary submits a prior authorization request with incomplete documentation, a detailed decision letter will be sent to the submitter (and, upon request, to the beneficiary if he or she was not the original submitter) with an explanation of what information is missing. The facility or beneficiary can rectify the situation and resubmit the prior authorization request with appropriate documentation.
- Scenario 4: When a facility renders a service that is subject to the prior authorization process to a beneficiary, and submits the claim to the MAC for payment without requesting a prior authorization, the claim will be stopped for prepayment review and documentation will be requested.

++ If the claim is determined to be not medically necessary or to be insufficiently documented, the claim will be denied, and all current policies and procedures regarding liability for payment will apply. The facility and/or beneficiary can appeal the claim denial if they believe the denial was inappropriate.

++ If the claim is determined to be payable, it will be paid.

Under the model, we will work to limit any adverse impact on beneficiaries and to educate beneficiaries about the process. If a prior authorization request is not affirmed, and the claim is still submitted by the facility, the claim will be denied in full, but beneficiaries will continue to have all applicable administrative appeal rights.

Only one prior authorization request per beneficiary per designated time period can be provisionally affirmed. If the initial facility cannot complete the total number of HBO treatments (for example, the initial facility closes or the beneficiary moves out of the area), the initial request is cancelled. In this situation, a subsequent prior authorization request may be submitted for the same beneficiary and must include the required documentation in the submission. If multiple facilities are providing HBO treatments to the beneficiary during the same or overlapping time period, the prior authorization decision will only cover the facility indicated in the provisionally affirmed prior authorization request. Any facility submitting claims for which no prior authorization request is recorded will be subject to 100 percent pre-payment medical review of those claims.

Additional information is available on the CMS Web site at *http://go.cms.gov/PAHBO.*

III. Collection of Information Requirements

Section 1115A(d)(3) of the Act, as added by section 3021 of the Affordable Care Act, states that chapter 35 of title 44, United States Code (the Paperwork Reduction Act of 1995), shall not apply to the testing and evaluation of models or expansion of such models under this section. Consequently, this document need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Authority: Section 1115A of the Social Security Act.

Dated: October 8, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–27578 Filed 11–20–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1464–N]

Medicare Program; Town Hall Meeting on FY 2016 Applications for New Medical Services and Technology Add-On Payments

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a Town Hall meeting in accordance with section 1886(d)(5)(K)(viii) of the Social Security Act (the Act) to discuss fiscal year (FY) 2016 applications for add-on payments for new medical services and technologies under the hospital inpatient prospective payment systems (IPPS). Interested parties are invited to this meeting to present their comments, recommendations, and data regarding whether the FY 2016 new medical services and technologies applications meet the substantial clinical improvement criterion.

DATES: *Meeting Date:* The Town Hall Meeting announced in this notice will be held on Tuesday, February 3, 2015. The Town Hall Meeting will begin at 9:00 a.m. Eastern Standard Time (e.s.t.) and check-in will begin at 8:30 a.m. e.s.t.

Deadline for Registration for Participants (not Presenting) at the Town Hall Meeting and Submitting Requests for Special Accommodations: Registration to attend the Town Hall Meeting and requests for special accommodations must be received no later than 5:00 p.m. Tuesday, January 20, 2015.

Deadline for Registration of Presenters at the Town Hall Meeting: Registration to present at the Town Hall Meeting must be received no later than 5:00 p.m. e.s.t. on Monday, January 19, 2015.

Deadline for Submission of Agenda Item(s) or Written Comments for the Town Hall Meeting: Written comments and agenda items for discussion at the Town Hall Meeting, including agenda items by presenters, must be received no later than 5:00 p.m. e.s.t. Monday, January 19, 2015. In addition to materials submitted for discussion at the Town Hall Meeting, individuals may submit other written comments after the Town Hall Meeting, as specified in the **ADDRESSES** section of this notice, on whether the service or technology represents a substantial clinical improvement. These comments must be received no later than 5:00 p.m. e.s.t on Tuesday, February 24, 2015, for consideration in the FY 2016 IPPS proposed rule.

ADDRESSES: *Meeting Location:* The Town Hall Meeting will be held in the main Auditorium in the central building of the Centers for Medicare and Medicaid Services located at 7500 Security Boulevard, Baltimore, MD 21244–1850.

In addition, we are providing two alternatives to attending the meeting in person—(1) there will be an open toll-free phone line to call into the Town Hall Meeting; or (2) participants may view and participate in the Town Hall Meeting via live stream technology and/or webinar. Information on these options is provided in section II.B. of this notice.

Registration and Special Accommodations: Individuals wishing to participate in the meeting must register by following the on-line registration instructions located in section III. of this notice or by contacting staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individuals who need special accommodations should contact staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Submission of Agenda Item(s) or Written Comments for the Town Hall Meeting: Each presenter must submit an agenda item(s) regarding whether a FY 2016 application meets the substantial clinical improvement criterion. Agenda items, written comments, questions or other statements must not exceed three single-spaced typed pages and may be sent via email to *newtech@cms.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Michael Treitel, (410) 786–4552, *michael.treitel@cms.hhs.gov*, or Celeste Beauregard, (410) 786–8102, *celeste.beauregard@cms.hhs.gov.* Alternatively, you may forward your requests via email to *newtech@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on the Add-On Payments for New Medical Services and Technologies Under the IPPS

Sections 1886(d)(5)(K) and (L) of the Social Security Act (the Act) require the Secretary to establish a process of identifying and ensuring adequate payments to acute care hospitals for new medical services and technologies under Medicare. Effective for discharges beginning on or after October 1, 2001, section 1886(d)(5)(K)(i) of the Act requires the Secretary to establish (after notice and opportunity for public comment) a mechanism to recognize the costs of new services and technologies under the hospital inpatient prospective payment system (IPPS). In addition, section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered ''new'' if it meets criteria established by the Secretary (after notice and opportunity for public comment). (See the FY 2002 IPPS proposed rule (66 FR 22693, May 4, 2001) and final rule (66 FR 46912, September 7, 2001) for a more detailed discussion.)

In the September 7, 2001 final rule (66 FR 46914), we noted that we evaluated a request for special payment for a new medical service or technology against the following criteria in order to determine if the new technology meets the substantial clinical improvement requirement:

- The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
- The device offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.
- Use of the device significantly improves clinical outcomes for a patient population as compared to currently available treatments. Some examples of outcomes that are frequently evaluated in studies of medical devices are the following:

++ Reduced mortality rate with use of the device.

++ Reduced rate of device-related complications.

++ Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).

++ Decreased number of future hospitalizations or physician visits.

++ More rapid beneficial resolution of the disease process treatment because of the use of the device.

++ Decreased pain, bleeding or other quantifiable symptoms.

++ Reduced recovery time.

In addition, we indicated that the requester is required to submit evidence that the technology meets one or more of these criteria.

Section 503 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1886(d)(5)(K)(viii) of the Act to revise the process for evaluating new medical services and technology applications by requiring the Secretary to do the following:

- Provide for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries before publication of a proposed rule.
- Make public and periodically update a list of all the services and technologies for which an application is pending.
- Accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial improvement.
- Provide for a meeting at which organizations representing hospitals, physicians, manufacturers and any other interested party may present comments, recommendations, and data to the clinical staff of CMS as to whether the service or technology represents a substantial improvement before publication of a proposed rule.

The opinions and recommendations provided during this meeting will assist us as we evaluate the new medical services and technology applications for fiscal year (FY) 2016. In addition, they will help us to evaluate our policy on the IPPS new technology add-on payment process before the publication of the FY 2016 IPPS proposed rule.

II. Town Hall Meeting and Conference Calling/Live Streaming Information

A. Format of the Town Hall Meeting

As noted in section I. of this notice, we are required to provide for a meeting at which organizations representing hospitals, physicians, manufacturers and any other interested party may present comments, recommendations, and data to the clinical staff of CMS concerning whether the service or technology represents a substantial clinical improvement. This meeting will allow for a discussion of the substantial clinical improvement criteria for each of the FY 2016 new medical services and technology add-on payment applications. Information regarding the applications can be found on our Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.*

The majority of the meeting will be reserved for presentations of comments, recommendations, and data from registered presenters. The time for each presenter's comments will be approximately 10 to 15 minutes and will be based on the number of registered presenters. Presenters will be scheduled to speak in the order in which they register and grouped by new technology applicant. Therefore, individuals who would like to present must register and submit their agenda item(s) via email to *newtech@cms.hhs.gov* by the date specified in the **DATES** section of this notice.

In addition, written comments will also be accepted and presented at the meeting if they are received via email to *newtech@cms.hhs.gov* by the date specified in the **DATES** section of this notice. Written comments may also be submitted after the meeting for our consideration. If the comments are to be considered before the publication of the proposed rule, the comments must be received via email to *newtech@cms.hhs.gov* by the date specified in the **DATES** section of this notice.

B. Conference Call, Live Streaming, and Webinar Information

For participants who cannot attend the Town Hall Meeting in person, an open toll-free phone line, (877) 267–1577, has been made available. The Meeting Place meeting ID is 993 601 192.

Also, there will be an option to view and participate in the Town Hall Meeting via live streaming technology and/or a webinar. Information on the option to participate via live streaming technology and/or a webinar will be provided through an upcoming listserv notice and posted on the New Technology Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.* Continue to check the Web site for updates.

Disclaimer: We cannot guarantee the reliability of live streaming technology and/or a webinar.

III. Registration Instructions

The Division of Acute Care in CMS is coordinating the meeting registration for the Town Hall Meeting for the FY 2016 Applications for New Medical Services and Technology Add-On Payments on substantial clinical improvement. While there is no registration fee, individuals planning to attend the Town Hall Meeting in person must register to attend.

Registration may be completed on-line at the following web address: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.* Select the link at the bottom of the page ''Register to Attend the New Technology Town Hall Meeting''. After completing the registration, on-line registrants should print the confirmation page(s) and bring it with them to the meeting(s).

If you are unable to register on-line, you may register by sending an email to *newtech@cms.hhs.gov.* Please include your name, address, telephone number, email address, and fax number. If seating capacity has been reached, you will be notified that the meeting has reached capacity.

IV. Security, Building, and Parking Guidelines

Because this meeting will be located on Federal property, for security reasons, any persons wishing to attend this meeting must register by the date specified in the **DATES** section of this notice. Please allow sufficient time to go through the security checkpoints. It is suggested that you arrive at 7500 Security Boulevard no later than 8:30 a.m. e.s.t.

Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Passing through a metal detector and inspection of items brought into the building. We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting in person. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting(s).

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building. Seating capacity is limited to the first 250 registrants.

Authority: Section 503 of Pub. L. 108–173.

Dated: October 28, 2014.

Marilyn Tavenner,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2014–27579 Filed 11–20–14; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB No.: 0970–0401.

Description: Executive Order 12862 directs Federal agencies to provide service to the public that matches or exceeds the best service available in the private sector. In order to work continuously to ensure that the Administration for Children and Families' programs are effective and meet our customers' needs we use a generic clearance process to collect qualitative feedback on our service delivery. This collection of information is necessary to enable ACF to garner customer and stakeholder feedback in an efficient timely manner, in accord with our commitment to improving service delivery. The information collected from our customers and stakeholders will help ensure that users have an effective, efficient and satisfying experience with the programs. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service,

or focus attention on areas where communication, training or change in operation might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between ACF and its customer and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

This request is an extension of the ''generic fast-track'' process offered to all government agencies by OMB in 2010. Fast-track means each request receives approval five days after submission, if no issues are brought to ACF's attention by OMB within the five days.

Respondents

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Survey	5,000	1	0.5	2,500

Estimated Total Annual Burden Hours:

In compliance with the requirements of Section 506(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, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–27558 Filed 11–20–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0510]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Prohibited From Use in Animal Food or Feed

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing 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 recordkeeping requirements for substances prohibited for use in animal food or feed.

DATES: Submit electronic or written comments on the collection of information by January 20, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: 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.

Substances Prohibited From Use in Animal Food or Feed—21 CFR Part 589 (OMB Control Number 0910–0627—Revision)

This regulation prohibits the use of certain cattle origin materials in the food or feed of all animals to help prevent the spread of bovine spongiform encephalopathy (BSE) in United States' cattle. BSE is a progressive and fatal neurological disorder of cattle that results from an unconventional transmissible agent. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). All TSEs affect the central nervous system of infected animals. These measures will further strengthen existing safeguards against BSE.

Description of Recordkeeping for Respondents: Rendering facilities, medicated feed manufacturers, livestock feeders.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section 589.2001; substances prohibited from use in animal food or feed	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours	Operating and maintenance costs
589.2001(c)(2)(vi) and (c)(3)(i)	175	1	175	20	3,500	$59,500
589.2001(c)(2)(ii)	50	1	50	20	1,000	17,000
589.2001(c)(3)(i)(A)	175	1	175	26	4,550	80,580
Total					9,050	157,080

[1] There are no capital costs associated with this collection of information.

The number of recordkeepers times the number of records per recordkeeper equals total annual records. Total annual records times average burden per recordkeeper equals total hours.

Description of Respondents for Reporting: The final regulation on BSE (73 FR 22720) included a provision that exempts cattle materials prohibited in animal feed (CMPAF) from designated countries from the prohibition on its use in animal feed. A foreign country seeking this designation will submit a written request to FDA that includes a variety of information about the country's BSE status (§ 589.2001(f)). During the past 6 years, FDA received 2 requests from countries to be exempted from CMPAF restrictions.

FDA estimates the reporting burden for this information collection as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section 589.2001(f)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per respondent	Total hours
One-time (initial) burden	1	1	1	80	80
Burden from future review	1	1	1	26	26

[1] There are no capital costs or operating costs associated with the collection of information.

One-Time (initial) Reporting Burden

There will be a one-time burden to countries that apply to FDA seeking to be designated as not subject to restrictions applicable to CMPAF. We estimate that each country that applies for an exclusion will spend 80 hours putting information together to submit to FDA. Table 2 row 1 presents the one-time burden for the exclusion. (See final BSE regulation at 73 FR 22754).

Recurring Burden

Countries that successfully petition FDA to be designated as exempt from certain BSE-related restrictions applicable to animal feed will be subject to future review by FDA to ensure that their designation remains appropriate. As part of this process, FDA may ask designated countries from time to time to confirm that their BSE situation and the information submitted by them in support of their original application remains unchanged. We assume it will take FDA and the designated country undergoing a review in the future about one third the time and effort it did when the information was submitted. Table 2 row 2 presents the expected recurring burden.

Dated: November 17, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27518 Filed 11–20–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0535]

Agency Information Collection Activities; Proposed Collection; Comment Request; Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on our 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. This notice invites comments on the collection of information associated with the submission of notifications of health claims or nutrient content claims based on authoritative statements of scientific bodies of the U.S. Government.

DATES: Submit either electronic or written comments on the collection of information by January 20, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: 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, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of our functions, including whether the information will have practical utility; (2) the accuracy of our 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.

Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body—(OMB Control Number 0910–0374)—Extension

Section 403(r)(2)(G) and (r)(3)(C) of the Federal Food, Drug and Cosmetic Act (the FD&C Act) (21 U.S.C. 343(r)(2)(G) and (r)(3)(C)), as amended by the FDA Modernization Act of 1997, provides that any person may market a food product whose label bears a nutrient content claim or a health claim that is based on an authoritative statement of a scientific body of the U.S. Government or the National Academy of Sciences (NAS). Under this section of the FD&C Act, a person that intends to use such a claim must submit a notification of its intention to use the claim 120 days before it begins marketing the product bearing the claim. In the **Federal Register** of June 11, 1998 (63 FR 32102), we announced the availability of a guidance entitled ''Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body.'' The guidance provides the Agency's interpretation of terms central to the submission of a notification and the Agency's views on the information that should be included in the notification. We believe that the guidance will enable persons to meet the criteria for notifications that are established in section 403(r)(2)(G) and (r)(3)(C) of the FD&C Act. In addition to the information specifically required by the FD&C Act to be in such notifications, the guidance states that the notifications should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. We intend to review the notifications we receive to ensure that they comply with the criteria established by the FD&C Act.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section of the FD&C Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
403(r)(2)(G) (nutrient content claims)	1	1	1	250	250
403(r)(2)(C) (health claims)	1	1	1	450	450
Guidance for Notifications	2	1	2	1	2
Total					702

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on our experience with health claims, nutrient content claims, and other similar notification procedures that fall under our jurisdiction. To avoid estimating the number of respondents as zero, we estimate that there will be one or fewer respondents annually for nutrient content claim and health claim notifications. We estimate that we will receive one nutrient content claim notification and one health claim notification per year over the next 3 years.

Section 403(r)(2)(G) and (r)(3)(C) of the FD&C Act requires that the notification include the exact words of the claim, a copy of the authoritative statement, a concise description of the basis upon which such person relied for determining that this is an authoritative statement as outlined in the FD&C Act, and a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which a health claim refers or to the nutrient level to which the nutrient content claim refers. This balanced representation of the scientific literature is expected to include a bibliography of the scientific literature on the topic of the claim and a brief, balanced account or analysis of how this literature either supports or fails to support the authoritative statement.

Since the claims are based on authoritative statements of a scientific body of the U.S. Government or NAS, we believe that the information that is required by the FD&C Act to be submitted with a notification will be readily available to a respondent. However, the respondent will have to collect and assemble that information. Based on communications with firms that have submitted notifications, we estimate that one respondent will take 250 hours to collect and assemble the information required by the statute for a nutrient content claim notification. Further, we estimate that one respondent will take 450 hours to collect and assemble the information required by the statute for a health claim notification.

Under the guidance, notifications should also contain information on analytical methodology for the nutrient that is the subject of a claim based on an authoritative statement. The guidance applies to both nutrient content claim and health claim notifications. We have determined that this information should be readily available to a respondent and, thus, we estimate that it will take a respondent 1 hour to incorporate the information into each notification. We expect there will be two respondents for a total of 2 hours.

Dated: November 17, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27517 Filed 11–20–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 1999–D–3528 (Formerly Docket No. 1999D–5046)]

Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture; Guidance for Industry'' dated December 2014. The guidance document provides manufacturers of licensed whole blood and blood components intended for transfusion or for further manufacture, including source plasma, with recommendations concerning submission of changes to an approved biologics license application (BLA). The guidance document also provides manufacturers of licensed whole blood and blood components recommendations in connection with the applicability and content of comparability protocols and labeling changes. The guidance applies to the manufacture and distribution of licensed products. The guidance announced in this notice finalizes the draft guidance of the same title dated June 2013 and supersedes the document of the same title dated July 2001 (July 2001 guidance).

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to 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 the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jonathan McKnight, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture; Guidance for Industry'' dated December 2014. The guidance document provides manufacturers of licensed whole blood and blood components intended for transfusion or for further manufacture, including source plasma, with recommendations concerning submission of changes to an approved BLA in accordance with the requirements under Title 21 of the Code of Federal Regulations 601.12 (21 CFR 601.12). The guidance document also provides manufacturers of licensed whole blood and blood components with recommendations in connection with the applicability and content of comparability protocols under § 601.12(e) and labeling changes under § 601.12(f). Frequently, a manufacturer of a licensed product determines that it is appropriate to make a change in its product, production process, quality controls, equipment, facilities, responsible personnel, or labeling as documented in its approved BLA(s). Section 601.12 states the requirements to report such changes for licensed biological products to FDA.

The recommendations contained in the guidance document reflect current FDA and industry experience with reporting changes to an approved application, including reporting the implementation of new technologies. The recommendations have been revised for reporting categories for certain changes to an approved application that were in the July 2001 guidance based on the experience gained over the last decade.

In the **Federal Register** of May 31, 2013 (78 FR 32668), FDA announced the availability of the draft guidance of the same title dated June 2013. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In response to comments, the guidance includes the addition of numerous appendices with tables to highlight the appropriate reporting categories related to certain manufacturing changes. The guidance announced in this notice finalizes the draft guidance dated June 2013.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. 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

The 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 601.12 and Form FDA 356h have been approved under OMB control number 0910–0338; the collections of information in 21 CFR 607.26 and Form FDA 2830 have been approved under OMB control number 0910–0052; the collections of information in 21 CFR 606.121, 606.170, and 610.40 have been approved under OMB control number 0910–0116; and the collections of information in 21 CFR 600.14 have been approved under OMB control number 0910–0458.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: November 17, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27521 Filed 11–20–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0502]

Report on the Standardization of Risk Evaluation and Mitigation Strategies; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice entitled ''Report on the Standardization of Risk Evaluation and Mitigation Strategies'' that appeared in the **Federal Register** of September 23, 2014. The document misstated the name of an organization. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Richard Currey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6125, Silver Spring, MD 20993–0002, 301–796–3918, FAX: 301–595–7910, *REMS_Standardization@fda.hhs.gov;* or Adam Kroetsch, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring, MD 20993–0002; 301–796–3842, FAX: 301–847–8443, *REMS_Standardization@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 23, 2014 (79 FR 56816), in FR Doc. 2014–22513, the following correction is made:

1. On page 56817, in the third column, under ''Draft Report Describing Findings Concerning REMS Standardization and Plans for Projects to Standardize REMS,'' ''Accreditation Commission for Education in Nursing'' is corrected to read ''American Nurses Credentialing Center.''

Dated: November 17, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27522 Filed 11–20–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Developing and Using Precision Therapies in the ''Omics'' Era: Generating and Interpreting Evidence for Rare Subsets; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a public workshop entitled ''Developing and Using Precision Therapies in the 'Omics' Era: Generating and Interpreting Evidence for Rare Subsets.'' This public workshop is being cosponsored with the Center for Translational and Regulatory Sciences at the University of Virginia (UVA). The goals of this public workshop are to facilitate discussion on current scientific approaches using rare subsets during drug development programs and to further seek input from multiple stakeholders on approaches to obtain evidence that inform the regulatory evaluation of therapeutic products in rare subsets of patients identified through in-vitro diagnostic testing when specific, controlled trials are not feasible.

DATES: The public workshop will be held on December 12, 2014, from 9 a.m. to 5 p.m. Individuals who wish to attend the public workshop in person or via a live Webcast must register online by December 1, 2014, at: *https://www.signup4.net/Public/ap.aspx?OID=130&EID=DEVE96E.* Section II of this document provides attendance and registration information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Padmaja Mummaneni, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2164, Silver Spring, MD 20993–0002, 301–796–2027, email: *padmaja.mummaneni@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Therapeutic products are increasingly targeted to patients who have molecular characteristics that are diagnostic of a particular subtype of disease, prognostic for better or worse outcomes, or predictive of treatment response. The advent of next-generation sequencing and other high throughput technologies has enabled the development of in-vitro diagnostic tests that are able to detect rare molecular variations, specifically in the patient, tumor, or microbial DNA sequence. FDA and UVA are cosponsoring an open public workshop among stakeholders in the pharmaceutical industry, representatives from academia, regulatory scientists, and other interested parties on the development and usage of diagnostic and therapeutic products that respectively have the potential to identify and treat patients with rare molecular characteristics. It is important for regulatory agencies, pharmaceutical and diagnostic industries, and the medical community, including payers, to have a mutual

understanding of various forms of evidence that could inform regulatory and medical decision making. The public workshop will help identify key components of such an evidence framework when therapeutic effectiveness is being evaluated in patients with molecular characteristics that are rare or have not been studied in clinical trials.

II. Attendance and Registration

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Individuals who wish to attend the public workshop must register on or before December 1, 2014, by visiting: *https://www.signup4.net/Public/ap.aspx?OID=130&EID=DEVE96E.*

Early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. On-site registration on the day of the public workshop will be based on space availability.

FDA will provide additional background information at the time the **Federal Register** notice is published and an agenda approximately 2 weeks before the public workshop at the FDA Meeting Information page, which is available online at: *http://wcms.fda.gov/FDAgov/Drugs/NewsEvents/ucm416622.htm?SSContributor=true.*

If you need special accommodations because of disability, please contact Padmaja Mummaneni (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the public workshop.

A live Webcast of this public workshop will be viewable on Adobe Connect at *https://collaboration.fda.gov/rsw2014/* on the day of the public workshop.

Dated: November 17, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27523 Filed 11–20–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 22, 2015, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Jennifer Shepherd, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *AIDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug applications (NDAs) 207–500 and 207–501, isavuconazonium sulfate capsules and isavuconazonium sulfate for injection, sponsored by Astellas Pharma Global Development, Inc., respectively for the proposed indications of treatment of invasive aspergillosis and mucormycosis.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 7, 2015. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 29, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 30, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jennifer Shepherd at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 17, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–27573 Filed 11–20–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 79 FR 63412–63414 dated October 23, 2014).

This notice reflects organizational changes in the Health Resources and Services Administration (HRSA). Specifically, this notice abolishes the Division of Global Training and Development and transfers the Global Health Workforce Training Programs from the Bureau of Health Workforce (RQ) to the HIV/AIDS Bureau (RV).

Chapter RQ—Bureau of Health Workforce

Section RQ–20, Functions

Delete the functions for the Office of Global Health Affairs (RQA1) within the Bureau of Health Workforce (RQ) and replace in its entirety.

Office of Global Health Affairs (RQA1)

The Office of Global Health Affairs serves as the principal advisor to the Office of Workforce Development and Analysis Director and the Associate Administrator on global health issues. Specifically: (1) Provides leadership, coordination, and advancement of global health activities relating to health care services for vulnerable and at-risk populations and for HRSA training programs; (2) provides support for the agency's International Visitors Program; (3) develops linkages and facilitates a mutual exchange of expertise for domestic and international programs aimed at improving quality and innovation in health professions education, retention, training, faculty development and community based systems of care; (4) provides leadership within HRSA for the support of global health and coordinates policy development with the HHS Office of Global Health Affairs and other departmental agencies, and; (5) supports and conducts programs with respect to activities associated with the international migration, domestic training, and utilization of foreign medical graduates and U.S. citizens studying abroad.

Chapter RV—HIV/AIDS Bureau

Section RV–20, Functions

Delete the functions for the Division of HIV/AIDS Training and Capacity Development (RV7) within the HIV/AIDS Bureau (RV) and replace in its entirety.

Division of HIV/AIDS Training and Capacity Development (RV7)

The Division of HIV/AIDS Training and Capacity Development provides national leadership and manages the implementation of Part F under Title XXVI of the PHS Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009, P.L. 111–87 (the Ryan White HIV/AIDS Program), including the Special Projects of National Significance and the AIDS Education and Training Centers Programs. The Special Projects of National Significance Program develops innovative models of HIV care and the AIDS Education and Training Centers Program increases the number of health care providers who are educated and motivated to counsel, diagnose, treat, and medically manage people with HIV disease and to help prevent high-risk behaviors that lead to HIV transmission. The division also implements the training and systems strengthening functions of the Global HIV/AIDS Program as part of the President's Emergency Plan for AIDS Relief (PEPFAR). This includes strengthening health systems for delivery of prevention, care and treatment services for people living with HIV/AIDS in PEPFAR funded countries and providing management and oversight of international programs aimed at improving quality and innovation in health professions education and training. The division will translate lessons learned from both the Global HIV/AIDS Programs and Special Projects of National Significance projects to the Part A, B, C, D, and F grantee community. In collaboration with the Division of Policy and Data, the division assesses effectiveness of technical assistance efforts/initiatives, identifies new technical assistance needs and priority areas, and participates in the bureau-wide technical assistance workgroup.

Section RV–30, Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is effective upon date of signature.

Dated: November 16, 2014.

Mary K. Wakefield,

Administrator.

[FR Doc. 2014–27563 Filed 11–20–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Application for Collaboration With the Therapeutic Development Branch (TDB), Division of Preclinical Innovation (DPI), National Center for Advancing Translational Sciences (NCATS)

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Nora Yang, Therapeutic Development Branch, DPI, NCATS, NIH, 9800 Medical Center Drive, Building B, Rockville, MD 20850, or call non-toll-free number (301) 217–1077, or Email your request, including your address to: *TRND@mail.nih.gov.* Formal requests for additional plans and

instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Application for Collaboration with the Therapeutic Development Branch (TDB), Division of Preclinical Innovation (DPI), National Center for Advancing Translational Sciences (NCATS), 0925–0658, Expiration Date 06/30/2015—EXTENSION, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH).

Need and Use of Information Collection: The Therapeutic Development Branch (TDB) provides opportunities to partner with and gain access to a variety of programs delivering assay development, screening, hit-to-lead chemistry, lead optimization, chemical biology studies, drug development capabilities, expertise, and clinical/regulatory resources in a collaborative environment, with the goal of moving promising therapeutics into human clinical trials for both common and specifically rare and/or neglected diseases. The TDB uses an application and evaluation process to select collaborators. Selected investigators provide the drug project starting points and ongoing biological/disease expertise throughout the project. The application and evaluation process is necessary to determine amount and quality of current data, select meritorious projects for adoption, and to serve as a basis for determining specific scientific gaps to be filled.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The estimated annualized burden hours are 510.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
TDB Project Information Template	170	1	1	170
Online Collaborator Solicitation (TRND)	100	1	1	100
Online Collaborator Solicitation (BrIDGs)	70	1	1	70
Solicitation Instructions (TRND)	100	1	1	100
Solicitation Instructions (BrIDGs)	70	1	1	70

Dated: October 29, 2014.

M. Janis Mullaney,

Associate Director for Administration, NCATS, NIH.

[FR Doc. 2014–27636 Filed 11–20–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NIH)

Summary: The National Institutes of Health (NIH), Office of the Director (OD), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on the ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery '' for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et. seq.). This collection was developed as part of a Federal Government-wide effort to streamline the process for seeking feedback from the public on service delivery. This notice announces our intent to submit this collection to OMB for approval and solicits comments on specific aspects for the proposed information collection.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Ms. Mikia P. Currie, Program Analyst, Office of Policy for Extramural Research Administration, 6705 Rockledge Drive, Suite 350, Bethesda, Maryland 20892, or call a non-toll-free number 301–435–0941 or Email your request, including your address to *curriem@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NIH), 0925–0648, Expiration Date 1/31/2015, EXTENSION, National Institutes of Health (NIH), Office of the Director (OD).

Need and Use of Information Collection: We are not requesting changes for this submission. The proposed information collection activity provides a means to garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions. This information, however, is not statistical surveys that yield quantitative results, which can be generalized to the population of study. This feedback will provide information about the NIH's customer or stakeholder perceptions, experiences, and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative, and actionable communications between the NIH and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the NIH's services will be unavailable.

The NIH will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collections are voluntary;

• The collections are low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and are low-cost for both the respondents and the Federal Government;
• The collections are non-controversial and do not raise issues of concern to other Federal agencies;
• Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
• Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
• Information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency;
• Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
• Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

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 Office of Management and Budget control number.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 4,358.

Estimated Annualized Burden Hours

ESTIMATED ANNUAL REPORTING BURDEN

Type of collection	Number of respondents	Annual frequency per response	Hours per response	Total hours
Customer Satisfaction Surveys	1,000	1	30/60	500
In-Depth Interviews (IDIs) or Small Discussion Groups	1,000	1	90/60	1,500
Focus Groups	1,000	1	90/60	1,500
Usability and Pilot Testing	150,000	1	5/60	12,525
Conference/Training—Pre and Post Surveys	100,000	2	10/60	33,333
Total				49,358

Dated: November 13, 2014.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2014–27637 Filed 11–20–14; 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; Neuropharmacology.

Date: December 12, 2014.

Time: 12:00 p.m. to 2:00 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: Richard D. Crosland, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4190, MSC 7850, Bethesda, MD 20892, 301–435–1220, *crosland@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neuropsychiatric Mechanisms.

Date: December 12, 2014.

Time: 12:30 p.m. to 1:30 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: Deborah L. Lewis, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4183, MSC 7850, Bethesda, MD 20892, 301–408–9129, *lewisdeb@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: November 17, 2014.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–27561 Filed 11–20–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2551–14; DHS Docket No. USCIS–2014–0011]

RIN 1615–ZB33

Designation of Liberia for Temporary Protected Status

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Through this Notice, the Department of Homeland Security (DHS) announces that the Secretary of Homeland Security (Secretary) has designated Liberia for Temporary Protected Status (TPS) for a period of 18 months, effective November 21, 2014 through May 21, 2016. Under section 244(b)(1)(C) of the Immigration and Nationality Act (INA), 8 U.S.C. 1254a(b)(1)(C), the Secretary is authorized to designate a foreign state (or any part thereof) for TPS upon finding that the foreign state is experiencing extraordinary and temporary conditions that prevent its nationals from returning in safety and that permitting such aliens to remain temporarily in the United States is not contrary to the national interest.

This designation allows eligible Liberian nationals (and aliens having no nationality who last habitually resided in Liberia) who have continuously resided in the United States since November 20, 2014 and been continuously physically present in the United States since November 21, 2014 to be granted TPS. This Notice also describes the other eligibility criteria applicants must meet.

Individuals who believe they may qualify for TPS under this designation may apply within the 180-day registration period that begins on November 21, 2014 and ends on May 20, 2015. They may also apply for Employment Authorization Documents (EADs) and for travel authorization. Through this Notice, DHS also sets forth the procedures for nationals of Liberia (or aliens having no nationality who last habitually resided in Liberia) to apply for TPS, EADs, and travel authorization with U.S. Citizenship and Immigration Services (USCIS).

Given the Ebola Virus Disease (EVD)-related basis for the designations of Liberia, Guinea, and Sierra Leone for TPS and ongoing efforts to prevent the spread of EVD, requests for advance travel authorization (''advance parole'') for travel to one or more of these three countries will not be approved, as a matter of discretion, absent extraordinary circumstances. If you depart from the United States without obtaining advance parole or you do not comply with any conditions that may be placed on your advance parole document, you may not be permitted to re-enter the United States. TPS beneficiaries who are granted advance parole to travel to Liberia, Guinea or Sierra Leone are advised that they, like other aliens granted advance parole, are not guaranteed parole into the United States. A separate decision regarding your ability to enter will be made when you arrive at a port-of-entry upon your return. Individuals considering travel outside the United States should visit the Department of State's Web site for the most up-to-date information in Travel Alerts and Warnings and in the Ebola Fact Sheet for Travelers.

DATES: This designation of Liberia for TPS is effective on November 21, 2014 and will remain in effect through May 21, 2016. The 180-day registration period for eligible individuals to submit TPS applications begins November 21, 2014, and will remain in effect through May 20, 2015.

FOR FURTHER INFORMATION CONTACT:

- For further information on TPS, including guidance on the application process and additional information on eligibility, please visit the USCIS TPS Web page at *http://www.uscis.gov/tps.*

You can find specific information about this designation of Liberia for TPS by selecting ''TPS Designated Country: Liberia'' from the menu on the left of the TPS Web page.

- You can also contact the TPS Operations Program Manager at the Family and Status Branch, Service Center Operations Directorate, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue NW., Washington, DC 20529–2060; or by phone at (202) 272–1533 (this is not a toll-free number). **Note:** The phone number provided here is solely for questions regarding this TPS Notice. It is not for individual case status inquires.

- Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at 800–375–5283 (TTY 800–767–1833). Service is available in English and Spanish.

- Further information will also be available at local USCIS offices upon publication of this Notice.

SUPPLEMENTARY INFORMATION:

Table of Abbreviations

BIA—Board of Immigration Appeals
DHS—Department of Homeland Security
DOS—Department of State
EAD—Employment Authorization Document
EVD—Ebola Virus Disease
FNC—Final Nonconfirmation
IJ—Immigration Judge
INA—Immigration and Nationality Act
OSC—U.S. Department of Justice, Office of Special Counsel for Immigration-Related Unfair Employment Practices
SAVE—USCIS Systematic Alien Verification for Entitlements Program
Secretary—Secretary of Homeland Security
TNC—Tentative Nonconfirmation
TPS—Temporary Protected Status
TTY—Text Telephone
USCIS—U.S. Citizenship and Immigration Services
WHO—World Health Organization

What is Temporary Protected Status (TPS)?

- TPS is a temporary immigration status granted to eligible nationals of a country designated for TPS under the INA, or to eligible persons without nationality who last habitually resided in the designated country.
- During the TPS designation period, TPS beneficiaries are eligible to remain in the United States, may not be removed, and are authorized to work and to obtain EADs, so long as they continue to meet the requirements of TPS.
- TPS beneficiaries may be granted travel authorization as a matter of discretion. Given the EVD-related basis for the designations of Liberia, Guinea, and Sierra Leone for TPS and ongoing efforts to prevent the spread of EVD, requests for advance travel authorization (''advance parole'') for travel to one or more of these three countries will not be approved, as a matter of discretion, absent extraordinary circumstances. If you depart from the United States without obtaining advance parole or you do not comply with any conditions that may be placed on your advance parole document, you may not be permitted to re-enter the United States. TPS beneficiaries who are granted advance parole to travel to Liberia, Guinea or Sierra Leone are advised that they, like other aliens granted advance parole, are not guaranteed parole into the United States. A separate decision regarding your ability to enter will be made when you arrive at a port-of-entry upon your return. Individuals considering travel outside the United States should visit the Department of State's Web site for the most up-to-date information in Travel Alerts and Warnings and in the Ebola Fact Sheet for Travelers.
- The granting of TPS does not result in or lead to permanent resident status.
- When the Secretary terminates a country's TPS designation through a separate **Federal Register** notice, beneficiaries return to the same immigration status they maintained before TPS, if any (unless that status has since expired or been terminated), or to any other lawfully obtained immigration status they received while registered for TPS.

What authority does the Secretary have to designate Liberia for TPS?

Section 244(b)(1) of the INA, 8 U.S.C. 1254a(b)(1), authorizes the Secretary, after consultation with appropriate U.S. Government agencies, to designate a foreign state (or part thereof) for TPS if the Secretary finds that certain country conditions exist.[1] The Secretary can designate a foreign state for TPS based on one of three circumstances. One circumstance is if ''there exist extraordinary and temporary conditions in the foreign state that prevent aliens who are nationals of the state from returning to the state in safety, unless the [Secretary] finds that permitting the aliens to remain temporarily in the United States is contrary to the national interest of the United States.'' INA section 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C).

Following the designation of a foreign state for TPS, the Secretary may then grant TPS to eligible nationals of that foreign state (or aliens having no nationality who last habitually resided in that state). *See* INA section 244(a)(1)(A), 8 U.S.C. 1254a(a)(1)(A). Applicants must demonstrate that they satisfy all eligibility criteria, including that they have been ''continuously physically present'' in the United States since the effective date of the designation, which is either the date of the **Federal Register** Notice announcing the designation or such later date as the Secretary may determine, and that they have ''continuously resided'' in the United States since such date as the Secretary may designate. *See* INA section 244(a)(1)(A), (b)(2)(A), (c)(1)(A)(i–ii); 8 U.S.C. 1254a(a)(1)(A), (b)(2)(A), (c)(1)(A)(i–ii).

Why is the Secretary designating Liberia for TPS through May 21, 2016?

The Secretary has determined, after consultation with the Department of State (DOS) and other appropriate Government agencies, that there exist extraordinary and temporary conditions in Liberia that prevent Liberian nationals (and persons having no nationality who last habitually resided in Liberia) from returning in safety. The Secretary also has determined that permitting such aliens to remain temporarily in the United States would not be contrary to the national interest of the United States.

On November 7, 2014 the World Health Organization (WHO) reported that as of November 4, 2014 there had been 13,241 cases of EVD in Guinea, Liberia, and Sierra Leone, with 4,950 deaths, making the 2014 EVD epidemic the largest in history. The outbreak began in Guinea in March 2014 and spread to Liberia and Sierra Leone.

The course of the EVD epidemic currently cannot be predicted accurately as cases of EVD continue to rise every day. As of November 4, 2014 there are numerous areas in each of the three countries where transmission continues to occur at high rates. Large scale efforts to control the epidemic in Guinea, Liberia, and Sierra Leone are ongoing to address these hotspots. As of November 4, 2014, the WHO reported a total of 6,619 cases occurring in Liberia, resulting in 2,766 deaths. Ebola is a highly infectious, severe, and acute viral illness with a high fatality rate. Although experimental treatments and vaccines are under development, there are currently no approved vaccines or approved antivirals for treatment of the disease. It is unlikely that a medical vaccine or cure could be produced on a large scale in the near future.

The WHO noted that the outbreak in Liberia is ''by far the most worrisome.'' As of November 2014, all of Liberia's 15 districts have reported confirmed cases. On October 1, 2014, the WHO reported that the situation in Liberia, and in Monrovia in particular, continued to deteriorate. Compelling evidence from responders and laboratory staff in Liberia indicates that there is widespread under-reporting of new cases. With a recent influx of additional response support during October and November 2014 from the United States and other nations, at least 2 districts appeared to have some leveling off or decrease in cases. Despite this positive change, the situation remains dire as new cases continue to pop up daily across the country.

On July 27, 2014, the President of Liberia ordered the closure of schools, placed non-essential government workers on a mandatory 30-day leave, and ordered the closure of all markets along Liberia's borders with Sierra Leone and Guinea. In September 2014, the World Bank predicted that by the end of 2015, Guinea, Sierra Leone, and Liberia could potentially lose a total of $809 million in their economies due to the West African Ebola outbreak. Many countries in the region have closed borders and implemented travel bans to and from Guinea, Liberia, and Sierra Leone.

The EVD epidemic has overwhelmed the already weak health care systems in Liberia and Sierra Leone, and placed Guinea's system under great strain. As of November 4, 2014, the WHO reports that, 545 health care workers are known to have developed EVD (88 in Guinea, 318 in Liberia, 11 in Nigeria, and 128 in Sierra Leone). Three hundred and

[1] As of March 1, 2003, in accordance with section 1517 of title XV of the Homeland Security Act of 2002, Public Law 107–296, 116 Stat. 2135, any reference to the Attorney General in a provision of the INA describing functions transferred from the Department of Justice to DHS ''shall be deemed to refer to the Secretary'' of Homeland Security. *See* 6 U.S.C. 557 (codifying the Homeland Security Act of 2002, tit. XV, section 1517).

eleven health care workers have died as a result of EVD infection. Fears of transmission, overcrowding, and inadequate medical and protective supplies have resulted in patients refraining from seeking care and doctors and nurses refusing to work. Individuals in these countries are increasingly unable to get treatment for preventable or treatable conditions, such as malaria, diarrheal diseases, and pregnancy complications. Maternal and child health care is being especially undermined. Attempted containment measures such as cancellation of airline flights, international trade restrictions, and disruption to agriculture threaten future food shortages and have added to the suffering caused by the EVD epidemic.

Based upon this review and after consultation with appropriate Government agencies, the Secretary finds that:

- Liberian nationals (and persons without nationality who last habitually resided in Liberia) cannot return to Liberia in safety due to extraordinary and temporary conditions. *See* INA section 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C);
- It is not contrary to the national interest of the United States to permit nationals of Liberia (and persons without nationality who last habitually resided in Liberia) who meet the eligibility requirements of TPS to remain in the United States temporarily. *See* INA section 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C);
- The designation of Liberia for TPS will be for an 18-month period from November 21, 2014 through May 21, 2016. *See* INA section 244(b)(2), 8 U.S.C. 1254a(b)(2);
- Applicants for TPS under the designation of Liberia must demonstrate that they have been continuously residing in the United States since November 20, 2014. *See* INA section 244(c)(1)(A)(ii), 8 U.S.C. 1254a(c)(1)(A)(i);
- Applicants for TPS under the designation of Liberia must demonstrate that they have been continuously physically present in the United States since November 21, 2014, the effective date of this designation of Liberia for TPS. *See* INA section 244(b)(2)(A), (c)(1)(A)(i); 8 U.S.C. 1254a(b)(2)(A), (c)(1)(A)(i); and
- An estimated 4,000 Liberian nationals (and persons without nationality who last habitually resided in Liberia) are (or are likely to become) eligible for TPS under this designation.

Notice of the Designation of Liberia for TPS

By the authority vested in me as Secretary under INA section 244, 8 U.S.C. 1254a, after consultation with the appropriate U.S. Government agencies, I designate Liberia for TPS under INA section 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C), for a period of 18 months from November 21, 2014 through May 21, 2016.

Jeh Charles Johnson,

Secretary.

Required Application Forms and Application Fees To Register for TPS

To register for TPS for Liberia, an applicant must submit each of the following two applications:

1. Application for Temporary Protected Status (Form I–821) with the form fee; and
2. Application for Employment Authorization (Form I–765).

- For administrative purposes, an applicant must submit an Application for Employment Authorization (Form I–765) even if no EAD is requested.
- If you want an EAD, you must pay the Application for Employment Authorization (Form I–765) fee only if you are age 14 through 65.
- No application fee for Employment Authorization (Form I–765) is required for an EAD with an initial TPS application if you are under the age of 14 or over the age of 65.

You must submit both completed application forms together. If you are unable to pay the required fees, you may apply for a waiver for these application fees and/or the biometrics services fee described below by completing a Request for Fee Waiver (Form I–912), or submitting a personal letter requesting a fee waiver, and providing satisfactory supporting documentation. For more information on the application forms and fees for TPS, please visit the USCIS TPS Web page at *http://www.uscis.gov/tps*. Fees for Application for Temporary Protected Status (Form I–821), Application for Employment Authorization (Form I–765), and biometric services are also described in 8 CFR 103.7(b).

Biometric Services Fee

Biometrics (such as fingerprints) are required for all applicants 14 years of age or older. Those applicants must submit a biometric services fee. As previously stated, if you are unable to pay for the biometric services fee, you may request a fee waiver by completing a Request for Fee Waiver (Form I–912) or by submitting a personal letter requesting a fee waiver, and providing satisfactory supporting documentation. For more information on the biometric services fee, please visit the USCIS Web site at *http://www.uscis.gov.* If necessary, you may be required to visit an Application Support Center to have your biometrics captured.

Re-Filing a TPS Application After Receiving a Denial of a Fee Waiver Request

If you request a fee waiver when filing your TPS and EAD application forms and your request is denied, you may re-file your application packet with the correct fees before the filing deadline of May 20, 2015. If you attempt to submit your application with a fee waiver request before the initial filing deadline, but you receive your application back with the USCIS fee waiver denial, and there are fewer than 45 days before the filing deadline (or the deadline has passed), you may still re-file your application within the 45-day period after the date on the USCIS fee waiver denial notice. You must include the correct fees, or file a new fee waiver request. Your application will not be rejected even if the deadline has passed, provided it is mailed within those 45 days and all other required information for the application is included. Please be aware that if you re-file your TPS application packet with a new fee waiver request after the deadline based on this guidance and that new fee waiver request is denied, you cannot re-file again. **Note:** Alternatively, you may pay the TPS application fee and biometrics fee (if age 14 or older) but wait to request an EAD and pay the EAD application fee after USCIS grants your TPS application.

Mailing Information

Mail your application for TPS to the proper address in Table 1.

TABLE 1—MAILING ADDRESSES

If you:	Then mail your application to:
Would like to send your application by U.S. Postal Service	USCIS, P.O. Box 6943, Chicago, IL 60680–6943.

TABLE 1—MAILING ADDRESSES—Continued

If you:	Then mail your application to:
Would like to send your application by non-U.S. Postal Service courier	Attn: Liberia TPS, 131 S. Dearborn, 3rd Floor, Chicago, IL 60603–5517.

If you were granted TPS by an Immigration Judge (IJ) or the Board of Immigration Appeals (BIA), and you wish to request an EAD, please mail your application to the address in Table 1. Upon receiving a Receipt Notice from USCIS, please send an email to *TPSijgrant.tsc@uscis.dhs.gov* with the receipt number stating that you submitted a request for an EAD based on an IJ/BIA grant of TPS as USCIS may not have received records of your grant of TPS by either an IJ or the BIA. This will aid in the verification of your grant and processing of your application. You can find detailed information on what further information you need to email, and email addresses on the USCIS TPS Web page at *http://www.uscis.gov/tps.*

E-Filing

You cannot electronically file your application packet when applying for initial registration for TPS. Please mail your application packet to the mailing address listed in Table 1.

Supporting Documents

What type of basic supporting documentation must I submit?

To meet the basic eligibility requirements for TPS, you must submit evidence that you:

- Are a national of Liberia or an alien having no nationality who last habitually resided in Liberia. Such documents may include a copy of your passport if available, other documentation issued by the Government of Liberia showing your nationality (e.g., national identity card, official travel documentation issued by the Liberian Government), and/or your birth certificate with English translation accompanied by photo identification. USCIS will also consider certain forms of secondary evidence supporting your Liberian nationality. If the evidence presented is insufficient for USCIS to make a determination as to your nationality, USCIS may request additional evidence. If you cannot provide a passport, birth certificate with photo identification, or a national identity document with your photo or fingerprint, you must submit an affidavit showing proof of your unsuccessful efforts to obtain such documents and affirming that you are a national of Liberia. However, please be aware that an interview with an immigration officer will be required if you do not present any documentary proof of identity or nationality or if USCIS otherwise requests a personal appearance. *See* 8 CFR 103.2(b)(9), 244.9(a)(1);
- Have continuously resided in the United States since November 20, 2014. *See* INA section 244(c)(1)(A)(ii), 8 U.S.C. 1254a(c)(1)(A)(ii); 8 CFR 244.9(a)(2); and
- Have been continuously physically present in the United States since November 21, 2014, the effective date of the designation of Liberia. *See* INA section 244(b)(2)(A), (c)(1)(A)(i); 8 U.S.C. 1254a(b)(2)(A), (c)(1)(A)(i).

You must also present two color passport-style photographs of yourself. The filing instructions on the Application for Temporary Protected Status (Form I–821) list all the documents needed to establish basic eligibility for TPS. You may also find information on the acceptable documentation and other requirements for applying for TPS on the USCIS Web site at *www.uscis.gov/tps* under ''TPS Designated Country: Liberia.''

Do I need to submit additional supporting documentation?

If one or more of the questions listed in Part 4, Question 2 of the Application for Temporary Protected Status (Form I–821) applies to you, then you must submit an explanation on a separate sheet(s) of paper and/or additional documentation. Depending on the nature of the question(s) you are addressing, additional documentation alone may suffice, but usually a written explanation will also be needed.

Employment Authorization Document (EAD)

May I request an interim EAD at my local USCIS office?

No. USCIS will not issue interim EADs to TPS applicants at local offices.

When hired, what documentation may I show to my employer as proof of employment authorization and identity when completing Employment Eligibility Verification (Form I–9)?

You can find a list of acceptable document choices on the ''List of Acceptable Documents'' for Employment Eligibility Verification (Form I–9). You can find additional detailed information on the USCIS I–9 Central Web page at *http://www.uscis.gov/I-9Central.* Employers are required to verify the identity and employment authorization of all new employees by using the Employment Eligibility Verification (Form I–9). Within 3 days of hire, an employee must present proof of identity and employment authorization to his or her employer.

You may present any document from List A (reflecting both your identity and employment authorization), or one document from List B (reflecting identity) together with one document from List C (reflecting employment authorization). You may present an acceptable receipt for List A, List B, or List C documents as described in the Form I–9 Instructions. An EAD is an acceptable document under ''List A.'' Employers may not reject a document based on a future expiration date.

Can my employer require that I produce any other documentation to prove my status, such as proof of my Liberian citizenship?

No. When completing the Employment Eligibility Verification (Form I–9), including re-verifying employment authorization, employers must accept any documentation that appears on the ''Lists of Acceptable Documents'' for Employment Eligibility Verification (Form I–9) that reasonably appears to be genuine and that relates to you, or an acceptable List A, List B, or List C receipt. Employers may not request documentation that does not appear on the ''Lists of Acceptable Documents.'' Therefore, employers may not request proof of Liberian citizenship when completing the Employment Eligibility Verification (Form I–9) for new hires or reverifying the employment authorization of current employees. If presented with EADs that are unexpired on their face, employers should accept such EADs as valid ''List A'' documents so long as the EADs reasonably appear to be genuine and to relate to the employee. Refer to the ''Note to All Employees'' section for important information about your rights if your employer rejects lawful documentation, requires additional documentation, or otherwise discriminates against you because of

your citizenship or immigration status, or national origin.

Note to All Employers

Employers are reminded that the laws requiring proper employment eligibility verification and prohibiting unfair immigration-related employment practices remain in full force. This Notice does not supersede or in any way limit applicable employment verification rules and policy guidance, including those rules setting forth reverification requirements. For general questions about the employment eligibility verification process, employers may call USCIS at 888–464–4218 (TTY 877–875–6028) or email USCIS at *I-9Central@dhs.gov.* Calls and emails are accepted in English and many other languages. For questions about avoiding discrimination during the employment eligibility verification process, employers may also call the U.S. Department of Justice, Office of Special Counsel for Immigration-Related Unfair Employment Practices (OSC) Employer Hotline at 800–255–8155 (TTY 800–237–2515), which offers language interpretation in numerous languages, or email OSC at *osccrt@usdoj.gov.*

Note to Employees

For general questions about the employment eligibility verification process, employees may call USCIS at 888–897–7781 (TTY 877–875–6028) or email at *I-9Central@dhs.gov.* Calls are accepted in English and many other languages. Employees or applicants may also call the U.S. Department of Justice, Office of Special Counsel for Immigration-Related Unfair Employment Practices (OSC) Worker Information Hotline at 800–255–7688 (TTY 800–237–2515) for information regarding employment discrimination based upon citizenship status, immigration status, or national origin, or for information regarding discrimination related to Employment Eligibility Verification (Form I–9) and E-Verify. The OSC Worker Information Hotline provides language interpretation in numerous languages.

To comply with the law, employers must accept any document or combination of documents from the Lists of Acceptable Documents if the documentation reasonably appears to be genuine and to relate to the employee, or an acceptable List A, List B, or List C receipt described in the Employment Eligibility Verification (Form I–9) Instructions. Employers may not require extra or additional documentation beyond what is required for Employment Eligibility Verification (Form I–9) completion. Further, employers participating in E-Verify who receive an E-Verify case result of ''Tentative Nonconfirmation'' (TNC) must promptly inform employees of the TNC and give such employees an opportunity to contest the TNC. A TNC case result means that the information entered into E-Verify from Employment Eligibility Verification (Form I–9) differs from federal or state government records.

Employers may not terminate, suspend, delay training, withhold pay, lower pay or take any adverse action against an employee based on the employee's decision to contest a TNC or because the case is still pending with E-Verify. A Final Nonconfirmation (FNC) case result is received when E-Verify cannot verify an employee's employment eligibility. An employer may terminate employment based on a case result of FNC. Work-authorized employees who receive an FNC may call USCIS for assistance at 888–897–7781 (TTY 877–875–6028). An employee who believes he or she was discriminated against by an employer in the E-Verify process based on citizenship or immigration status, or based on national origin, may contact OSC's Worker Information Hotline at 800–255–7688 (TTY 800–237–2515). Additional information about proper nondiscriminatory Employment Eligibility Verification (Form I–9) and E-Verify procedures is available on the OSC Web site at *http://www.justice.gov/crt/about/osc/* and the USCIS Web site at *http://www.dhs.gov/E-verify.*

Note Regarding Federal, State, and Local Government Agencies (Such as Departments of Motor Vehicles)

While Federal Government agencies must follow the guidelines laid out by the Federal Government, State and local government agencies establish their own rules and guidelines when granting certain benefits. Each State may have different laws, requirements, and determinations about what documents you need to provide to prove eligibility for certain benefits. Whether you are applying for a Federal, State, or local government benefit, you may need to provide the government agency with documents that show you are a TPS beneficiary and/or show you are authorized to work based on TPS. Examples are:

(1) Your EAD that has a valid expiration date;

(2) A copy of your Form I–821 Approval Notice (Form I–797), if you receive one from USCIS.

Check with the government agency regarding which document(s) the agency will accept. You may also provide the agency with a copy of this **Federal Register** Notice.

Some benefit-granting agencies use the USCIS Systematic Alien Verification for Entitlements Program (SAVE) to verify the current immigration status of applicants for public benefits. If such an agency has denied your application based solely or in part on a SAVE response, the agency must offer you the opportunity to appeal the decision in accordance with the agency's procedures. If the agency has received and acted upon or will act upon a SAVE verification and you do not believe the response is correct, you may make an InfoPass appointment for an in-person interview at a local USCIS office. Detailed information on how to make corrections, make an appointment, or submit a written request to correct records under the Freedom of Information Act can be found at the SAVE Web site at *http://www.uscis.gov/save,* then by choosing ''How to Correct Your Records'' from the menu on the right.

[FR Doc. 2014–27772 Filed 11–20–14; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2553–14; DHS Docket No. USCIS–2014–0009]

RIN 1615–ZB34

Designation of Sierra Leone for Temporary Protected Status

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Through this Notice, the Department of Homeland Security (DHS) announces that the Secretary of Homeland Security (Secretary) has designated Sierra Leone for Temporary Protected Status (TPS) for a period of 18 months, effective November 21, 2014 through May 21, 2016. Under section 244(b)(1)(C) of the Immigration and Nationality Act (INA), 8 U.S.C. 1254a(b)(1)(C), the Secretary is authorized to designate a foreign state (or any part thereof) for TPS upon finding that the foreign state is experiencing extraordinary and temporary conditions that prevent its nationals from returning in safety and that permitting such aliens to remain temporarily in the United States is not contrary to the national interest.

This designation allows eligible Sierra Leonean nationals (and aliens having no nationality who last habitually resided in Sierra Leone) who have continuously resided in the United States since November 20, 2014 and been continuously physically present in the United States since November 21, 2014 to be granted TPS. This Notice also describes the other eligibility criteria applicants must meet.

Individuals who believe they may qualify for TPS under this designation may apply within the 180-day registration period that begins on November 21, 2014 and ends on May 20, 2015. They may also apply for Employment Authorization Documents (EADs) and for travel authorization. Through this Notice, DHS also sets forth the procedures for nationals of Sierra Leone (or aliens having no nationality who last habitually resided in Sierra Leone) to apply for TPS, EADs, and travel authorization with U.S. Citizenship and Immigration Services (USCIS).

Given the Ebola Virus Disease (EVD)-related basis for the designations of Liberia, Guinea, and Sierra Leone for TPS and ongoing efforts to prevent the spread of EVD, requests for advance travel authorization (''advance parole'') for travel to one or more of these three countries will not be approved, as a matter of discretion, absent extraordinary circumstances. If you depart from the United States without obtaining advance parole or you do not comply with any conditions that may be placed on your advance parole document, you may not be permitted to re-enter the United States. TPS beneficiaries who are granted advance parole to travel to Liberia, Guinea or Sierra Leone are advised that they, like other aliens granted advance parole, are not guaranteed parole into the United States. A separate decision regarding your ability to enter will be made when you arrive at a port-of-entry upon your return. Individuals considering travel outside the United States should visit the Department of State's Web site for the most up-to-date information in Travel Alerts and Warnings and in the Ebola Fact Sheet for Travelers.

DATES: This designation of Sierra Leone for TPS is effective on November 21, 2014 and will remain in effect through May 21, 2016. The 180-day registration period for eligible individuals to submit TPS applications begins November 21, 2014, and will remain in effect through May 20, 2015.

FOR FURTHER INFORMATION CONTACT:

- For further information on TPS, including guidance on the application process and additional information on eligibility, please visit the USCIS TPS Web page at *http://www.uscis.gov/tps.* You can find specific information about this designation of Sierra Leone for TPS by selecting ''TPS Designated Country: Sierra Leone'' from the menu on the left of the TPS Web page.
- You can also contact the TPS Operations Program Manager at the Family and Status Branch, Service Center Operations Directorate, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue NW., Washington, DC 20529–2060; or by phone at (202) 272–1533 (this is not a toll-free number). Note: The phone number provided here is solely for questions regarding this TPS Notice. It is not for individual case status inquires.
- Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at 800–375–5283 (TTY 800–767–1833). Service is available in English and Spanish.
- Further information will also be available at local USCIS offices upon publication of this Notice.

SUPPLEMENTARY INFORMATION:

Table of Abbreviations

BIA—Board of Immigration Appeals
DHS—Department of Homeland Security
DOS—Department of State
EAD—Employment Authorization Document
EVD—Ebola Virus Disease
FNC—Final Nonconfirmation
IJ—Immigration Judge
INA—Immigration and Nationality Act
OSC—U.S. Department of Justice, Office of Special Counsel for Immigration-Related Unfair Employment Practices
SAVE—USCIS Systematic Alien Verification for Entitlements Program
Secretary—Secretary of Homeland Security
TNC—Tentative Nonconfirmation
TPS—Temporary Protected Status
TTY—Text Telephone
USCIS—U.S. Citizenship and Immigration Services
WHO—World Health Organization

What is Temporary Protected Status (TPS)?

- TPS is a temporary immigration status granted to eligible nationals of a country designated for TPS under the INA, or to eligible persons without nationality who last habitually resided in the designated country.
- During the TPS designation period, TPS beneficiaries are eligible to remain in the United States, may not be removed, and are authorized to work and to obtain EADs, so long as they continue to meet the requirements of TPS.
- TPS beneficiaries may be granted travel authorization as a matter of discretion. Given the EVD-related basis for the designations of Liberia, Guinea, and Sierra Leone for TPS and ongoing efforts to prevent the spread of EVD, requests for advance travel authorization (''advance parole'') for travel to one or more of these three countries will not be approved, as a matter of discretion, absent extraordinary circumstances. If you depart from the United States without obtaining advance parole or you do not comply with any conditions that may be placed on your advance parole document, you may not be permitted to re-enter the United States. TPS beneficiaries who are granted advance parole to travel to Liberia, Guinea or Sierra Leone are advised that they, like other aliens granted advance parole, are not guaranteed parole into the United States. A separate decision regarding your ability to enter will be made when you arrive at a port-of-entry upon your return. Individuals considering travel outside the United States should visit the Department of State's Web site for the most up-to-date information in Travel Alerts and Warnings and in the Ebola Fact Sheet for Travelers.
- The granting of TPS does not result in or lead to permanent resident status.
- When the Secretary terminates a country's TPS designation through a separate **Federal Register** notice, beneficiaries return to the same immigration status they maintained before TPS, if any (unless that status has since expired or been terminated), or to any other lawfully obtained immigration status they received while registered for TPS.

What authority does the Secretary have to designate Sierra Leone for TPS?

Section 244(b)(1) of the INA, 8 U.S.C. 1254a(b)(1), authorizes the Secretary, after consultation with appropriate U.S. Government agencies, to designate a foreign state (or part thereof) for TPS if the Secretary finds that certain country conditions exist.[1] The Secretary can designate a foreign state for TPS based on one of three circumstances. One circumstance is if ''there exist extraordinary and temporary conditions

[1] As of March 1, 2003, in accordance with section 1517 of title XV of the Homeland Security Act of 2002, Public Law 107–296, 116 Stat. 2135, any reference to the Attorney General in a provision of the INA describing functions transferred from the Department of Justice to DHS ''shall be deemed to refer to the Secretary'' of Homeland Security. *See* 6 U.S.C. 557 (codifying the Homeland Security Act of 2002, tit. XV, section 1517).

in the foreign state that prevent aliens who are nationals of the state from returning to the state in safety, unless the [Secretary] finds that permitting the aliens to remain temporarily in the United States is contrary to the national interest of the United States.'' INA section 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C).

Following the designation of a foreign state for TPS, the Secretary may then grant TPS to eligible nationals of that foreign state (or aliens having no nationality who last habitually resided in that state). *See* INA section 244(a)(1)(A), 8 U.S.C. 1254a(a)(1)(A). Applicants must demonstrate that they satisfy all eligibility criteria, including that they have been ''continuously physically present'' in the United States since the effective date of the designation, which is either the date of the **Federal Register** Notice announcing the designation or such later date as the Secretary may determine, and that they have ''continuously resided'' in the United States since such date as the Secretary may designate. *See* INA section 244(a)(1)(A), (b)(2)(A), (c)(1)(A)(i–ii); 8 U.S.C. 1254a(a)(1)(A), (b)(2)(A), (c)(1)(A)(i–ii).

Why is the Secretary designating Sierra Leone for TPS through May 21, 2016?

The Secretary has determined, after consultation with the Department of State (DOS) and other appropriate Government agencies, that there exist extraordinary and temporary conditions in Sierra Leone that prevent Sierra Leonean nationals (and persons having no nationality who last habitually resided in Sierra Leone) from returning in safety. The Secretary also has determined that permitting such aliens to remain temporarily in the United States would not be contrary to the national interest of the United States.

On November 7, 2014 the World Health Organization (WHO) reported that as of November 4, 2014 there had been 13,241 cases of EVD in Guinea, Liberia, and Sierra Leone with 4,950 deaths, making the 2014 EVD epidemic the largest in history. The outbreak began in Guinea in March 2014 and spread to Liberia and Sierra Leone.

The course of the EVD epidemic currently cannot be predicted accurately as cases of EVD continue to rise every day. As of November 4, 2014 there are numerous areas in each of the three countries where transmission continues to occur at high rates. Large scale efforts to control the epidemic in Guinea, Liberia, and Sierra Leone are ongoing to address these hotspots. As of November 4, 2014 WHO reported a total of 4,862 Ebola cases occurring in Sierra Leone, resulting in 1,130 deaths. Ebola is a highly infectious, severe, and acute viral illness with a high fatality rate. Although experimental treatments and vaccines are under development, there are currently no approved vaccines or approved antivirals for treatment of the disease. It is unlikely that a medical vaccine or cure could be produced on a large scale in the near future.

On June 11, 2014, Sierra Leone shut its borders to trade with Liberia and Guinea and closed schools, cinemas, and nightclubs in order to prevent the spread of EVD. On July 30, 2014, the President of Sierra Leone proclaimed a state of public emergency. In order to combat the spread of the virus, the Sierra Leonean Government established new protocols for arriving and departing passengers at Freetown-Lungi International Airport, instituted restrictions on public and other mass gatherings, and implemented quarantine measures and travel restrictions for communities affected by EVD. The Government also required all deaths be reported before burial, authorized police and military personnel to aid in enforcing prevention and control measures, and directed local government officials to establish by-laws to support EVD prevention efforts. Between September 19 and 21, 2014, Sierra Leone's Government instituted a three-day house-to-house search in an attempt to stem the outbreak. The Government declared the search a success based on the discovery of around 100 bodies and 200 suspected patients. On October 5, 2014, a third of Sierra Leone's population is reported to be under official quarantine.

In September 2014, the World Bank predicted that by the end of 2015, Guinea, Sierra Leone, and Liberia could potentially lose a total of $809 million in their economies due to the West African Ebola outbreak. Many countries in the region have closed borders and implemented travel bans to and from Guinea, Liberia, and Sierra Leone.

The EVD epidemic has overwhelmed the already weak health care systems in Liberia and Sierra Leone, and placed Guinea's system under great strain. As of November 4, 2014, the WHO reports that, 545 health care workers are known to have developed EVD (88 in Guinea, 318 in Liberia, 11 in Nigeria, and 128 in Sierra Leone). Three hundred and eleven health care workers have died as a result of EVD infection. Fears of transmission, overcrowding, and inadequate medical and protective supplies have resulted in patients refraining from seeking care and doctors and nurses refusing to work. Individuals in these countries are increasingly unable to get treatment for preventable or treatable conditions, such as malaria, diarrheal diseases, and pregnancy complications. Maternal and child health care is being especially undermined. Attempted containment measures such as cancellation of airline flights, international trade restrictions, and disruption to agriculture threaten future food shortages and have added to the suffering caused by the EVD epidemic.

Based upon this review and after consultation with appropriate Government agencies, the Secretary finds that:

- Sierra Leonean nationals (and persons without nationality who last habitually resided in Sierra Leone) cannot return to Sierra Leone in safety due to extraordinary and temporary conditions. *See* INA section 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C);
- It is not contrary to the national interest of the United States to permit nationals of Sierra Leone (and persons without nationality who last habitually resided in Sierra Leone) who meet the eligibility requirements of TPS to remain in the United States temporarily. *See* INA section 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C);
- The designation of Sierra Leone for TPS will be for an 18-month period from November 21, 2014 through May 21, 2016. *See* INA section 244(b)(2), 8 U.S.C. 1254a(b)(2);
- Applicants for TPS under the designation of Sierra Leone must demonstrate that they have been continuously residing in the United States since November 20, 2014. *See* INA section 244(c)(1)(A)(ii), 8 U.S.C. 1254a(c)(1)(A)(ii);
- Applicants for TPS under the designation of Sierra Leone must demonstrate that they have been continuously physically present in the United States since November 21, 2014, the effective date of this designation of Sierra Leone for TPS. *See* INA section 244(b)(2)(A), (c)(1)(A)(i); 8 U.S.C. 1254a(b)(2)(A), (c)(1)(A)(i); and
- An estimated 2,000 nationals of Sierra Leone (and persons without nationality who last habitually resided in Sierra Leone) are (or are likely to become) eligible for TPS under this designation.

Notice of the Designation of Sierra Leone for TPS

By the authority vested in me as Secretary under INA section 244, 8 U.S.C. 1254a, after consultation with the appropriate U.S. Government agencies, I designate Sierra Leone for TPS under INA section 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C), for a period of 18 months

from November 21, 2014 through May 21, 2016.

Jeh Charles Johnson,
Secretary.

Required Application Forms and Application Fees To Register for TPS

To register for TPS for Sierra Leone, an applicant must submit each of the following two applications:

1. Application for Temporary Protected Status (Form I–821) with the form fee; and
2. Application for Employment Authorization (Form I–765).

- For administrative purposes, an applicant must submit an Application for Employment Authorization (Form I–765) even if no EAD is requested.
- If you want an EAD you must pay the Application for Employment Authorization (Form I–765) fee only if you are age 14 through 65.
- No application fee for Employment Authorization (Form I–765) is required for an EAD with an initial TPS application if you are under the age of 14 or over the age of 65.

You must submit both completed application forms together. If you are unable to pay the required fees, you may apply for a waiver for these application fees and/or the biometrics services fee described below by completing a Request for Fee Waiver (Form I–912), or submitting a personal letter requesting a fee waiver, and providing satisfactory supporting documentation. For more information on the application forms and fees for TPS, please visit the USCIS TPS Web page at *http://www.uscis.gov/tps.* Fees for Application for Temporary Protected Status (Form I–821), Application for Employment Authorization (Form I–765), and biometric services are also described in 8 CFR 103.7(b).

Biometric Services Fee

Biometrics (such as fingerprints) are required for all applicants 14 years of age or older. Those applicants must submit a biometric services fee. As previously stated, if you are unable to pay for the biometric services fee, you may request a fee waiver by completing a Request for Fee Waiver (Form I–912) or by submitting a personal letter requesting a fee waiver, and providing satisfactory supporting documentation. For more information on the biometric services fee, please visit the USCIS Web site at *http://www.uscis.gov.* If necessary, you may be required to visit an Application Support Center to have your biometrics captured.

Re-Filing a TPS Application After Receiving a Denial of a Fee Waiver Request

If you request a fee waiver when filing your TPS and EAD application forms and your request is denied, you may refile your application packet with the correct fees before the filing deadline of May 20, 2015. If you attempt to submit your application with a fee waiver request before the initial filing deadline, but you receive your application back with the USCIS fee waiver denial, and there are fewer than 45 days before the filing deadline (or the deadline has passed), you may still refile your application within the 45-day period after the date on the USCIS fee waiver denial notice. You must include the correct fees, or file a new fee waiver request. Your application will not be rejected even if the deadline has passed, provided it is mailed within those 45 days and all other required information for the application is included. Please be aware that if you re-file your TPS application packet with a new fee waiver request after the deadline based on this guidance and that new fee waiver request is denied, you cannot re-file again. **Note:** Alternatively, you may pay the TPS application fee and biometrics fee (if age 14 or older) but wait to request an EAD and pay the EAD application fee after USCIS grants your TPS application.

Mailing Information

Mail your application for TPS to the proper address in Table 1.

TABLE 1—MAILING ADDRESSES

If you:	Then mail your application to:
Would like to send your application by U.S. Postal Service	USCIS, P.O. Box 6943, Chicago, IL 60680–6943.
Would like to send your application by non-U.S. Postal Service courier	Attn: Sierra Leone TPS, 131 S. Dearborn, 3rd Floor, Chicago, IL 60603–5517.

If you were granted TPS by an Immigration Judge (IJ) or the Board of Immigration Appeals (BIA), and you wish to request an EAD, please mail your application to the address in Table 1. Upon receiving a Receipt Notice from USCIS, please send an email to *TPSijgrant.tsc@uscis.dhs.gov* with the receipt number stating that you submitted a request for an EAD based on an IJ/BIA grant of TPS as USCIS may not have received records of your grant of TPS by either an IJ or the BIA. This will aid in the verification of your grant and processing of your application. You can find detailed information on what further information you need to email, and email addresses on the USCIS TPS Web page at *http://www.uscis.gov/tps.*

E-Filing

You cannot electronically file your application packet when applying for initial registration for TPS. Please mail your application packet to the mailing address listed in Table 1.

Supporting Documents

What type of basic supporting documentation must I submit?

To meet the basic eligibility requirements for TPS, you must submit evidence that you:

- Are a national of Sierra Leone or an alien having no nationality who last habitually resided in Sierra Leone. Such documents may include a copy of your passport if available, other documentation issued by the Government of Sierra Leone showing your nationality (e.g., national identity card, official travel documentation issued by the Government of Sierra Leone), and/or your birth certificate with English translation accompanied by photo identification. USCIS will also consider certain forms of secondary evidence supporting your Sierra Leonean nationality. If the evidence presented is insufficient for USCIS to make a determination as to your nationality, USCIS may request additional evidence. If you cannot provide a passport, birth certificate with photo identification, or a national identity document with your photo or fingerprint, you must submit an affidavit showing proof of your unsuccessful efforts to obtain such documents and affirming that you are a national of Sierra Leone. However, please be aware that an interview with an immigration officer will be required if you do not present any documentary proof of identity or nationality or if USCIS otherwise requests a personal appearance. *See* 8 CFR 103.2(b)(9), 244.9(a)(1);

• Have continuously resided in the United States since November 20, 2014. *See* INA section 244(c)(1)(A)(ii), 8 U.S.C. 1254a(c)(1)(A)(ii); 8 CFR 244.9(a)(2); and

• Have been continuously physically present in the United States since November 21, 2014, the effective date of the designation of Sierra Leone. *See* section 244(b)(2)(A), (c)(1)(A)(i) of the INA; 8 U.S.C. 1254a(b)(2)(A), (c)(1)(A)(i).

You must also present two color passport-style photographs of yourself. The filing instructions on the Application for Temporary Protected Status (Form I–821) list all the documents needed to establish basic eligibility for TPS. You may also find information on the acceptable documentation and other requirements for applying for TPS on the USCIS Web site at *www.uscis.gov/tps* under ''TPS Designated Country: Sierra Leone.''

Do I need to submit additional supporting documentation?

If one or more of the questions listed in Part 4, Question 2 of the Application for Temporary Protected Status (Form I–821) applies to you, then you must submit an explanation on a separate sheet(s) of paper and/or additional documentation. Depending on the nature of the question(s) you are addressing, additional documentation alone may suffice, but usually a written explanation will also be needed.

Employment Authorization Document (EAD)

May I request an interim EAD at my local USCIS office?

No. USCIS will not issue interim EADs to TPS applicants at local offices.

When hired, what documentation may I show to my employer as proof of employment authorization and identity when completing Employment Eligibility Verification (Form I–9)?

You can find a list of acceptable document choices on the ''List of Acceptable Documents'' for Employment Eligibility Verification (Form I–9). You can find additional detailed information on the USCIS I–9 Central Web page at *http://www.uscis.gov/I-9Central.* Employers are required to verify the identity and employment authorization of all new employees by using the Employment Eligibility Verification (Form I–9). Within 3 days of hire, an employee must present proof of identity and employment authorization to his or her employer.

You may present any document from List A (reflecting both your identity and employment authorization), or one document from List B (reflecting identity) together with one document from List C (reflecting employment authorization). You may present an acceptable receipt for List A, List B, or List C documents as described in the Form I–9 Instructions. An EAD is an acceptable document under ''List A.'' Employers may not reject a document based on a future expiration date.

Can my employer require that I produce any other documentation to prove my status, such as proof of my Sierra Leonean citizenship?

No. When completing the Employment Eligibility Verification (Form I–9), including re-verifying employment authorization, employers must accept any documentation that appears on the ''Lists of Acceptable Documents'' for Employment Eligibility Verification (Form I–9) that reasonably appears to be genuine and that relates to you, or an acceptable List A, List B, or List C receipt. Employers may not request documentation that does not appear on the ''Lists of Acceptable Documents.'' Therefore, employers may not request proof of Sierra Leonean citizenship when completing the Employment Eligibility Verification (Form I–9) for new hires or reverifying the employment authorization of current employees. If presented with EADs that are unexpired on their face, employers should accept such EADs as valid ''List A'' documents so long as the EADs reasonably appear to be genuine and to relate to the employee. Refer to the ''Note to All Employees'' section for important information about your rights if your employer rejects lawful documentation, requires additional documentation, or otherwise discriminates against you because of your citizenship or immigration status, or national origin.

Note to All Employers

Employers are reminded that the laws requiring proper employment eligibility verification and prohibiting unfair immigration-related employment practices remain in full force. This Notice does not supersede or in any way limit applicable employment verification rules and policy guidance, including those rules setting forth reverification requirements. For general questions about the employment eligibility verification process, employers may call USCIS at 888–464–4218 (TTY 877–875–6028) or email USCIS at *I-9Central@dhs.gov.* Calls and emails are accepted in English and many other languages. For questions about avoiding discrimination during the employment eligibility verification process, employers may also call the U.S. Department of Justice, Office of Special Counsel for Immigration-Related Unfair Employment Practices (OSC) Employer Hotline at 800–255–8155 (TTY 800–237–2515), which offers language interpretation in numerous languages, or email OSC at *osccrt@usdoj.gov.*

Note to Employees

For general questions about the employment eligibility verification process, employees may call USCIS at 888–897–7781 (TTY 877–875–6028) or email at *I-9Central@dhs.gov.* Calls are accepted in English and many other languages. Employees or applicants may also call the U.S. Department of Justice, Office of Special Counsel for Immigration-Related Unfair Employment Practices (OSC) Worker Information Hotline at 800–255–7688 (TTY 800–237–2515) for information regarding employment discrimination based upon citizenship status, immigration status, or national origin, or for information regarding discrimination related to Employment Eligibility Verification (Form I–9) and E-Verify. The OSC Worker Information Hotline provides language interpretation in numerous languages.

To comply with the law, employers must accept any document or combination of documents from the Lists of Acceptable Documents if the documentation reasonably appears to be genuine and to relate to the employee, or an acceptable List A, List B, or List C receipt described in the Employment Eligibility Verification (Form I–9) Instructions. Employers may not require extra or additional documentation beyond what is required for Employment Eligibility Verification (Form I–9) completion. Further, employers participating in E-Verify who receive an E-Verify case result of ''Tentative Nonconfirmation'' (TNC) must promptly inform employees of the TNC and give such employees an opportunity to contest the TNC. A TNC case result means that the information entered into E-Verify from Employment Eligibility Verification (Form I–9) differs from federal or state government records.

Employers may not terminate, suspend, delay training, withhold pay, lower pay or take any adverse action against an employee based on the employee's decision to contest a TNC or because the case is still pending with E-Verify. A Final Nonconfirmation (FNC) case result is received when E-Verify cannot verify an employee's employment eligibility. An employer

may terminate employment based on a case result of FNC. Work-authorized employees who receive an FNC may call USCIS for assistance at 888–897–7781 (TTY 877–875–6028). An employee who believes he or she was discriminated against by an employer in the E-Verify process based on citizenship or immigration status, or based on national origin, may contact OSC's Worker Information Hotline at 800–255–7688 (TTY 800–237–2515). Additional information about proper nondiscriminatory Employment Eligibility Verification (Form I–9) and E-Verify procedures is available on the OSC Web site at *http://www.justice.gov/crt/about/osc/* and the USCIS Web site at *http://www.dhs.gov/E-verify.*

Note Regarding Federal, State, and Local Government Agencies (Such as Departments of Motor Vehicles)

While Federal Government agencies must follow the guidelines laid out by the Federal Government, State and local government agencies establish their own rules and guidelines when granting certain benefits. Each State may have different laws, requirements, and determinations about what documents you need to provide to prove eligibility for certain benefits. Whether you are applying for a Federal, State, or local government benefit, you may need to provide the government agency with documents that show you are a TPS beneficiary and/or show you are authorized to work based on TPS. Examples are:

(1) Your EAD that has a valid expiration date;

(2) A copy of your Form I–821 Approval Notice (Form I–797), if you receive one from USCIS.

Check with the government agency regarding which document(s) the agency will accept. You may also provide the agency with a copy of this **Federal Register** Notice.

Some benefit-granting agencies use the USCIS Systematic Alien Verification for Entitlements Program (SAVE) to verify the current immigration status of applicants for public benefits. If such an agency has denied your application based solely or in part on a SAVE response, the agency must offer you the opportunity to appeal the decision in accordance with the agency's procedures. If the agency has received and acted upon or will act upon a SAVE verification and you do not believe the response is correct, you may make an InfoPass appointment for an in-person interview at a local USCIS office. Detailed information on how to make corrections, make an appointment, or submit a written request to correct records under the Freedom of Information Act can be found at the SAVE Web site at *http://www.uscis.gov/save,* then by choosing ''How to Correct Your Records'' from the menu on the right.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[CIS No. 2551–14; DHS Docket No. USCIS–2014–0010]

RIN 1615–ZB32

Designation of Guinea for Temporary Protected Status

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Through this Notice, the Department of Homeland Security (DHS) announces that the Secretary of Homeland Security (Secretary) has designated Guinea for Temporary Protected Status (TPS) for a period of 18 months, effective November 21, 2014 through May 21, 2016. Under section 244(b)(1)(C) of the Immigration and Nationality Act (INA), 8 U.S.C. 1254a(b)(1)(C), the Secretary is authorized to designate a foreign state (or any part thereof) for TPS upon finding that the foreign state is experiencing extraordinary and temporary conditions that prevent its nationals from returning in safety and that permitting such aliens to remain temporarily in the United States is not contrary to the national interest.

This designation allows eligible Guinean nationals (and aliens having no nationality who last habitually resided in Guinea) who have continuously resided in the United States since November 20, 2014 and been continuously physically present in the United States since November 21, 2014 to be granted TPS. This Notice also describes the other eligibility criteria applicants must meet.

Individuals who believe they may qualify for TPS under this designation may apply within the 180-day registration period that begins on November 21, 2014 and ends on May 20, 2015. They may also apply for Employment Authorization Documents (EADs) and for travel authorization. Through this Notice, DHS also sets forth the procedures for nationals of Guinea (or aliens having no nationality who last habitually resided in Guinea) to apply for TPS, EADs, and travel authorization with U.S. Citizenship and Immigration Services (USCIS).

Given the Ebola Virus Disease (EVD)-related basis for the designations of Liberia, Guinea, and Sierra Leone for TPS and ongoing efforts to prevent the spread of EVD, requests for advance travel authorization (''advance parole'') for travel to one or more of these three countries will not be approved, as a matter of discretion, absent extraordinary circumstances. If you depart from the United States without obtaining advance parole or you do not comply with any conditions that may be placed on your advance parole document, you may not be permitted to re-enter the United States. TPS beneficiaries who are granted advance parole to travel to Liberia, Guinea or Sierra Leone are advised that they, like other aliens granted advance parole, are not guaranteed parole into the United States. A separate decision regarding your ability to enter will be made when you arrive at a port-of-entry upon your return. Individuals considering travel outside the United States should visit the Department of State's Web site for the most up-to-date information in Travel Alerts and Warnings and in the Ebola Fact Sheet for Travelers.

DATES: This designation of Guinea for TPS is effective on November 21, 2014 and will remain in effect through May 21, 2016. The 180-day registration period for eligible individuals to submit TPS applications begins November 21, 2014, and will remain in effect through May 20, 2015.

FOR FURTHER INFORMATION CONTACT:

- For further information on TPS, including guidance on the application process and additional information on eligibility, please visit the USCIS TPS Web page at *http://www.uscis.gov/tps.*

You can find specific information about this designation of Guinea for TPS by selecting ''TPS Designated Country: Guinea'' from the menu on the left of the TPS Web page.

- You can also contact the TPS Operations Program Manager at the Family and Status Branch, Service Center Operations Directorate, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue NW., Washington, DC 20529–2060; or by phone at (202) 272–1533 (this is not a toll-free number). Note: The phone number provided here is solely for questions regarding this TPS Notice. It is not for individual case status inquires.

• Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at 800–375–5283 (TTY 800–767–1833). Service is available in English and Spanish.

• Further information will also be available at local USCIS offices upon publication of this Notice.

SUPPLEMENTARY INFORMATION:

Table of Abbreviations

BIA—Board of Immigration Appeals
DHS—Department of Homeland Security
DOS—Department of State
EAD—Employment Authorization Document
EVD—Ebola Virus Disease
FNC—Final Nonconfirmation
IJ—Immigration Judge
INA—Immigration and Nationality Act
OSC—U.S. Department of Justice, Office of Special Counsel for Immigration-Related Unfair Employment Practices
SAVE—USCIS Systematic Alien Verification for Entitlements Program
Secretary—Secretary of Homeland Security
TNC—Tentative Nonconfirmation
TPS—Temporary Protected Status
TTY—Text Telephone
USCIS—U.S. Citizenship and Immigration Services
WHO—World Health Organization

What is Temporary Protected Status (TPS)?

• TPS is a temporary immigration status granted to eligible nationals of a country designated for TPS under the INA, or to eligible persons without nationality who last habitually resided in the designated country.

• During the TPS designation period, TPS beneficiaries are eligible to remain in the United States, may not be removed, and are authorized to work and to obtain EADs, so long as they continue to meet the requirements of TPS.

• TPS beneficiaries may be granted travel authorization as a matter of discretion. Given the EVD-related basis for the designations of Liberia, Guinea, and Sierra Leone for TPS and ongoing efforts to prevent the spread of EVD, requests for advance travel authorization (''advance parole'') for travel to one or more of these three countries will not be approved, as a matter of discretion, absent extraordinary circumstances. If you depart from the United States without obtaining advance parole or you do not comply with any conditions that may be placed on your advance parole document, you may not be permitted to re-enter the United States. TPS beneficiaries who are granted advance parole to travel to Liberia, Guinea or Sierra Leone are advised that they, like other aliens granted advance parole, are not guaranteed parole into the United States. A separate decision regarding your ability to enter will be made when you arrive at a port-of-entry upon your return. Individuals considering travel outside the United States should visit the Department of State's Web site for the most up-to-date information in Travel Alerts and Warnings and in the Ebola Fact Sheet for Travelers.

• The granting of TPS does not result in or lead to permanent resident status.

• When the Secretary terminates a country's TPS designation through a separate **Federal Register** notice, beneficiaries return to the same immigration status they maintained before TPS, if any (unless that status has since expired or been terminated), or to any other lawfully obtained immigration status they received while registered for TPS.

What authority does the Secretary have to designate Guinea for TPS?

Section 244(b)(1) of the INA, 8 U.S.C. 1254a(b)(1), authorizes the Secretary, after consultation with appropriate U.S. Government agencies, to designate a foreign state (or part thereof) for TPS if the Secretary finds that certain country conditions exist.[1] The Secretary can designate a foreign state for TPS based on one of three circumstances. One circumstance is if ''there exist extraordinary and temporary conditions in the foreign state that prevent aliens who are nationals of the state from returning to the state in safety, unless the [Secretary] finds that permitting the aliens to remain temporarily in the United States is contrary to the national interest of the United States.'' INA section 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C).

Following the designation of a foreign state for TPS, the Secretary may then grant TPS to eligible nationals of that foreign state (or aliens having no nationality who last habitually resided in that state). *See* INA section 244(a)(1)(A), 8 U.S.C. 1254a(a)(1)(A). Applicants must demonstrate that they satisfy all eligibility criteria, including that they have been ''continuously physically present'' in the United States since the effective date of the designation, which is either the date of the **Federal Register** Notice announcing the designation or such later date as the Secretary may determine, and that they have ''continuously resided'' in the United States since such date as the Secretary may designate. *See* INA section 244(a)(1)(A), (b)(2)(A), (c)(1)(A)(i–ii); 8 U.S.C. 1254a(a)(1)(A), (b)(2)(A), (c)(1)(A)(i–ii).

Why is the Secretary designating Guinea for TPS through May 21, 2016?

The Secretary has determined, after consultation with the Department of State (DOS) and other appropriate Government agencies, that there exist extraordinary and temporary conditions in Guinea that prevent Guinean nationals (and persons having no nationality who last habitually resided in Guinea) from returning in safety. The Secretary also has determined that permitting such aliens to remain temporarily in the United States would not be contrary to the national interest of the United States.

On November 7, 2014 the World Health Organization (WHO) reported that as of November 4, 2014 there had been 13,241 cases of EVD in Guinea, Liberia, and Sierra Leone with 4,950 deaths, making the 2014 EVD epidemic the largest in history. The outbreak began in Guinea in March 2014 and spread to Liberia and Sierra Leone.

The course of the EVD epidemic currently cannot be predicted accurately as cases of EVD continue to rise every day. As of November 4, 2014 there are numerous areas in each of the three countries where transmission continues to occur at high rates. Large scale efforts to control the epidemic in Guinea, Liberia and Sierra Leone are ongoing to address these hotspots. As of November 4, 2014, the WHO reported a total of 1,760 EVD cases occurring in Guinea, resulting in 1,054 deaths. Ebola is a highly infectious, severe, and acute viral illness with a high fatality rate. Although experimental treatments and vaccines are under development, there are currently no approved vaccines or approved antivirals for treatment of the disease. It is unlikely that a medical vaccine or cure could be produced on a large scale in the near future.

As of November 4, 2014, 2014, the WHO stated that the rate of transmission in Guinea at the national level, although still of grave concern, appears to have stabilized. Transmission remains persistent in the Macenta district which accounted for more than half of the confirmed cases reported in Guinea in the previous week.

The Government of Guinea declared a public health emergency on August 14, 2014, and announced the

[1] As of March 1, 2003, in accordance with section 1517 of title XV of the Homeland Security Act of 2002, Public Law 107–296, 116 Stat. 2135, any reference to the Attorney General in a provision of the INA describing functions transferred from the Department of Justice to DHS ''shall be deemed to refer to the Secretary'' of Homeland Security. *See* 6 U.S.C. 557 (codifying the Homeland Security Act of 2002, tit. XV, section 1517).

implementation of preventive measures, including travel restrictions and a ban on transporting human remains between towns. Violence and distrust towards government and health care workers are among the largest barriers in controlling the EVD epidemic in Guinea. At least eight EVD aid workers have reportedly been killed in Guinea, and health workers in several parts of the country have reportedly endured vicious attacks by angry mobs and destruction of their vehicles, medicine, and equipment. More than half of the prefectures in Guinea have seen cases of Ebola as of November 7, 2014.

In September 2014, the World Bank predicted that by the end of 2015, Guinea, Sierra Leone, and Liberia could potentially lose a total of $809 million in their economies due to the West African Ebola outbreak. Many countries in the region have closed borders and implemented travel bans to and from Guinea, Liberia, and Sierra Leone.

The EVD epidemic has overwhelmed the already weak health care systems in Liberia and Sierra Leone, and placed Guinea's system under great strain. As of November 4, 2014, the WHO reports that, 545 health care workers are known to have developed EVD (88 in Guinea, 318 in Liberia, 11 in Nigeria, and 128 in Sierra Leone). Three hundred and eleven health care workers have died as a result of EVD infection. Fears of transmission, overcrowding, and inadequate medical and protective supplies have resulted in patients refraining from seeking care and doctors and nurses refusing to work. Individuals in these countries are increasingly unable to get treatment for preventable or treatable conditions, such as malaria, diarrheal diseases, and pregnancy complications. Maternal and child health care is being especially undermined. Attempted containment measures such as cancellation of airline flights, international trade restrictions, and disruption to agriculture threaten future food shortages and have added to the suffering caused by the EVD epidemic.

Based upon this review and after consultation with appropriate Government agencies, the Secretary finds that:

- Guinean nationals (and persons without nationality who last habitually resided in Guinea) cannot return to Guinea in safety due to extraordinary and temporary conditions. *See* INA section 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C);
- It is not contrary to the national interest of the United States to permit nationals of Guinea (and persons without nationality who last habitually resided in Guinea) who meet the eligibility requirements of TPS to remain in the United States temporarily. *See* INA section 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C);
- The designation of Guinea for TPS will be for an 18-month period from November 21, 2014 through May 21, 2016. *See* INA section 244(b)(2), 8 U.S.C. 1254a(b)(2);
- Applicants for TPS under the designation of Guinea must demonstrate that they have been continuously residing in the United States since November 20, 2014. *See* INA section 244(c)(1)(A)(ii), 8 U.S.C. 1254a(c)(1)(A)(ii);
- Applicants for TPS under the designation of Guinea must demonstrate that they have been continuously physically present in the United States since November 21, 2014, the effective date of this designation of Guinea for TPS. *See* INA section 244(b)(2)(A), (c)(1)(A)(i); 8 U.S.C. 1254a(b)(2)(A), (c)(1)(A)(i); and
- An estimated 2,000 nationals of Guinea (and persons without nationality who last habitually resided in Guinea) are (or are likely to become) eligible for TPS under this designation.

Notice of the Designation of Guinea for TPS

By the authority vested in me as Secretary under INA section 244, 8 U.S.C. 1254a, after consultation with the appropriate U.S. Government agencies, I designate Guinea for TPS under INA section 244(b)(1)(C), 8 U.S.C. 1254a(b)(1)(C), for a period of 18 months from November 21, 2014 through May 21, 2016.

Jeh Charles Johnson,

Secretary.

Required Application Forms and Application Fees To Register for TPS

To register for TPS for Guinea, an applicant must submit each of the following two applications:

1. Application for Temporary Protected Status (Form I–821) with the form fee; and
2. Application for Employment Authorization (Form I–765).

- For administrative purposes, an applicant must submit an Application for Employment Authorization (Form I–765) even if no EAD is requested.
- If you want an EAD you must pay the Application for Employment Authorization (Form I–765) fee only if you are age 14 through 65.
- No application fee for Employment Authorization (Form I–765) is required for an EAD with an initial TPS application if you are under the age of 14 or over the age of 65.

You must submit both completed application forms together. If you are unable to pay the required fees, you may apply for a waiver for these application fees and/or the biometrics services fee described below by completing a Request for Fee Waiver (Form I–912), or submitting a personal letter requesting a fee waiver, and providing satisfactory supporting documentation. For more information on the application forms and fees for TPS, please visit the USCIS TPS Web page at *http://www.uscis.gov/tps.* Fees for the Application for Temporary Protected Status (Form I–821), Application for Employment Authorization (Form I–765), and biometric services are also described in 8 CFR 103.7(b).

Biometric Services Fee

Biometrics (such as fingerprints) are required for all applicants 14 years of age or older. Those applicants must submit a biometric services fee. As previously stated, if you are unable to pay for the biometric services fee, you may request a fee waiver by completing a Request for Fee Waiver (Form I–912) or by submitting a personal letter requesting a fee waiver, and providing satisfactory supporting documentation. For more information on the biometric services fee, please visit the USCIS Web site at *http://www.uscis.gov.* If necessary, you may be required to visit an Application Support Center to have your biometrics captured.

Re-Filing a TPS Application After Receiving a Denial of a Fee Waiver Request

If you request a fee waiver when filing your TPS and EAD application forms and your request is denied, you may re-file your application packet with the correct fees before the filing deadline of May 20, 2015. If you attempt to submit your application with a fee waiver request before the initial filing deadline, but you receive your application back with the USCIS fee waiver denial, and there are fewer than 45 days before the filing deadline (or the deadline has passed), you may still re-file your application within the 45-day period after the date on the USCIS fee waiver denial notice. You must include the correct fees, or file a new fee waiver request. Your application will not be rejected even if the deadline has passed, provided it is mailed within those 45 days and all other required information for the application is included. Please be aware that if you re-file your TPS application packet with a new fee waiver request after the deadline based on this guidance and that new fee waiver request is denied, you cannot re-

file again. Note: Alternatively, you may pay the TPS application fee and biometrics fee (if age 14 or older) but wait to request an EAD and pay the EAD application fee after USCIS grants your TPS application.

Mailing Information

Mail your application for TPS to the proper address in Table 1.

TABLE 1—MAILING ADDRESSES

If you:	Then mail your application to:
Would like to send your application by U.S. Postal Service	USCIS, P.O. Box 6943, Chicago, IL 60680–6943.
Would like to send your application by non-U.S. Postal Service courier	Attn: Guinea TPS, 131 S. Dearborn 3rd Floor, Chicago, IL 60603–5517.

If you were granted TPS by an Immigration Judge (IJ) or the Board of Immigration Appeals (BIA), and you wish to request an EAD, please mail your application to the address in Table 1. Upon receiving a Receipt Notice from USCIS, please send an email to *TPSijgrant.tsc@uscis.dhs.gov* with the receipt number stating that you submitted a request for an EAD based on an IJ/BIA grant of TPS as USCIS may not have independently received a record of your grant of TPS by either an IJ or the BIA. This will aid in the verification of your grant and processing of your application. You can find detailed information on what further information you need to email, and email addresses on the USCIS TPS Web page at *http://www.uscis.gov/tps.*

E-Filing

You cannot electronically file your application packet when applying for initial registration for TPS. Please mail your application packet to the mailing address listed in Table 1.

Supporting Documents

What type of basic supporting documentation must I submit?

To meet the basic eligibility requirements for TPS, you must submit evidence that you:

- Are a national of Guinea or an alien having no nationality who last habitually resided in Guinea. Such documents may include a copy of your passport if available, other documentation issued by the Government of Guinea showing your nationality (e.g., national identity card, official travel documentation issued by the Government of Guinea), and/or your birth certificate with English translation accompanied by photo identification. USCIS will also consider certain forms of secondary evidence supporting your Guinean nationality. If the evidence presented is insufficient for USCIS to make a determination as to your nationality, USCIS may request additional evidence. If you cannot provide a passport, birth certificate with photo identification, or a national identity document with your photo or fingerprint, you must submit an affidavit showing proof of your unsuccessful efforts to obtain such documents and affirming that you are a national of Guinea. However, please be aware that an interview with an immigration officer will be required if you do not present any documentary proof of identity or nationality or if USCIS otherwise requests a personal appearance. *See* 8 CFR 103.2(b)(9), 244.9(a)(1);
- Have continuously resided in the United States since November 20, 2014. *See* INA section 244(c)(1)(A)(ii), 8 U.S.C. 1254a(c)(1)(A)(ii); 8 CFR 244.9(a)(2); and
- Have been continuously physically present in the United States since November 21, 2014, the effective date of the designation of Guinea. *See* INA section 244(b)(2)(A), (c)(1)(A)(i); 8 U.S.C. 1254a(b)(2)(A), (c)(1)(A)(i).

You must also present two color passport-style photographs of yourself. The filing instructions on the Application for Temporary Protected Status (Form I–821) list all the documents needed to establish basic eligibility for TPS. You may also find information on the acceptable documentation and other requirements for applying for TPS on the USCIS Web site at *www.uscis.gov/tps* under ''TPS Designated Country: Guinea.''

Do I need to submit additional supporting documentation?

If one or more of the questions listed in Part 4, Question 2 of the Application for Temporary Protected Status (Form I–821) applies to you, then you must submit an explanation on a separate sheet(s) of paper and/or additional documentation. Depending on the nature of the question(s) you are addressing, additional documentation alone may suffice, but usually a written explanation will also be needed.

Employment Authorization Document (EAD)

May I request an interim EAD at my local USCIS office?

No. USCIS will not issue interim EADs to TPS applicants at local offices.

When hired, what documentation may I show to my employer as proof of employment authorization and identity when completing Employment Eligibility Verification (Form I–9)?

You can find a list of acceptable document choices on the ''List of Acceptable Documents'' for Employment Eligibility Verification (Form I–9). You can find additional detailed information on the USCIS I–9 Central Web page at *http://www.uscis.gov/I-9Central.* Employers are required to verify the identity and employment authorization of all new employees by using the Employment Eligibility Verification (Form I–9). Within 3 days of hire, an employee must present proof of identity and employment authorization to his or her employer.

You may present any document from List A (reflecting both your identity and employment authorization), or one document from List B (reflecting identity) together with one document from List C (reflecting employment authorization). You may present an acceptable receipt for List A, List B, or List C documents as described in the Form I–9 Instructions. An EAD is an acceptable document under ''List A.'' Employers may not reject a document based on a future expiration date.

Can my employer require that I produce any other documentation to prove my status, such as proof of my Guinean citizenship?

No. When completing the Employment Eligibility Verification (Form I–9), including re-verifying employment authorization, employers must accept any documentation that appears on the ''Lists of Acceptable Documents'' for Employment Eligibility Verification (Form I–9) that reasonably appears to be genuine and that relates to

you, or an acceptable List A, List B, or List C receipt. Employers may not request documentation that does not appear on the ''Lists of Acceptable Documents.'' Therefore, employers may not request proof of Guinean citizenship when completing the Employment Eligibility Verification (Form I–9) for new hires or reverifying the employment authorization of current employees. If presented with EADs that are unexpired on their face, employers should accept such EADs as valid ''List A'' documents so long as the EADs reasonably appear to be genuine and to relate to the employee. Refer to the ''Note to All Employees'' section for important information about your rights if your employer rejects lawful documentation, requires additional documentation, or otherwise discriminates against you because of your citizenship or immigration status, or national origin.

Note to All Employers

Employers are reminded that the laws requiring proper employment eligibility verification and prohibiting unfair immigration-related employment practices remain in full force. This Notice does not supersede or in any way limit applicable employment verification rules and policy guidance, including those rules setting forth reverification requirements. For general questions about the employment eligibility verification process, employers may call USCIS at 888–464–4218 (TTY 877–875–6028) or email USCIS at *I-9Central@dhs.gov.* Calls and emails are accepted in English and many other languages. For questions about avoiding discrimination during the employment eligibility verification process, employers may also call the U.S. Department of Justice, Office of Special Counsel for Immigration-Related Unfair

Employment Practices (OSC) Employer Hotline at 800–255–8155 (TTY 800–237–2515), which offers language interpretation in numerous languages, or email OSC at *osccrt@usdoj.gov.*

Note to Employees

For general questions about the employment eligibility verification process, employees may call USCIS at 888–897–7781 (TTY 877–875–6028) or email at *I-9Central@dhs.gov.* Calls are accepted in English and many other languages. Employees or applicants may also call the U.S. Department of Justice, Office of Special Counsel for Immigration-Related Unfair Employment Practices (OSC) Worker Information Hotline at 800–255–7688 (TTY 800–237–2515) for information regarding employment discrimination based upon citizenship status, immigration status, or national origin, or for information regarding discrimination related to Employment Eligibility Verification (Form I–9) and E-Verify. The OSC Worker Information Hotline provides language interpretation in numerous languages.

To comply with the law, employers must accept any document or combination of documents from the Lists of Acceptable Documents if the documentation reasonably appears to be genuine and to relate to the employee, or an acceptable List A, List B, or List C receipt described in the Employment Eligibility Verification (Form I–9) Instructions. Employers may not require extra or additional documentation beyond what is required for Employment Eligibility Verification (Form I–9) completion. Further, employers participating in E-Verify who receive an E-Verify case result of ''Tentative Nonconfirmation'' (TNC) must promptly inform employees of the TNC and give such employees an opportunity to contest the TNC. A TNC case result means that the information entered into E-Verify from Employment Eligibility Verification (Form I–9) differs from federal or state government records.

Employers may not terminate, suspend, delay training, withhold pay, lower pay or take any adverse action against an employee based on the employee's decision to contest a TNC or because the case is still pending with E-Verify. A Final Nonconfirmation (FNC) case result is received when E-Verify cannot verify an employee's employment eligibility. An employer may terminate employment based on a case result of FNC. Work-authorized employees who receive an FNC may call USCIS for assistance at 888–897–7781 (TTY 877–875–6028). An employee who believes he or she was discriminated against by an employer in the E-Verify process based on citizenship or immigration status, or based on national origin, may contact OSC's Worker Information Hotline at 800–255–7688 (TTY 800–237–2515). Additional information about proper nondiscriminatory Employment Eligibility Verification (Form I–9) and E-Verify procedures is available on the OSC Web site at *http://www.justice.gov/crt/about/osc/* and the USCIS Web site at *http://www.dhs.gov/E-verify.*

Note Regarding Federal, State, and Local Government Agencies (Such as Departments of Motor Vehicles)

While Federal Government agencies must follow the guidelines laid out by the Federal Government, State and local government agencies establish their own rules and guidelines when granting certain benefits. Each State may have different laws, requirements, and determinations about what documents you need to provide to prove eligibility for certain benefits. Whether you are applying for a Federal, State, or local government benefit, you may need to provide the government agency with documents that show you are a TPS beneficiary and/or show you are authorized to work based on TPS. Examples are:

(1) Your EAD that has a valid expiration date;

(2) A copy of your Form I–821 Approval Notice (Form I–797), if you receive one from USCIS.

Check with the government agency regarding which document(s) the agency will accept. You may also provide the agency with a copy of this **Federal Register** Notice.

Some benefit-granting agencies use the USCIS Systematic Alien Verification for Entitlements Program (SAVE) to verify the current immigration status of applicants for public benefits. If such an agency has denied your application based solely or in part on a SAVE response, the agency must offer you the opportunity to appeal the decision in accordance with the agency's procedures. If the agency has received and acted upon or will act upon a SAVE verification and you do not believe the response is correct, you may make an InfoPass appointment for an in-person interview at a local USCIS office. Detailed information on how to make corrections, make an appointment, or submit a written request to correct records under the Freedom of Information Act can be found at the SAVE Web site at *http://www.uscis.gov/save,* then by choosing ''How to Correct Your Records'' from the menu on the right.

[FR Doc. 2014–27770 Filed 11–20–14; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0021]

Agency Information Collection Activities: Crew Member's Declaration

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Crew Member's Declaration (CBP Form 5129). CBP is proposing that this information collection be extended with no change to the burden hours or to the information collected. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before January 20, 2015 to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3507). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

Title: Crew Member's Declaration.

OMB Number: 1651–0021.

Form Number: Form 5129.

Abstract: CBP Form 5129, *Crew Member's Declaration,* is a declaration made by crew members listing all goods acquired abroad which are in his/her possession at the time of arrival in the United States. The data collected on CBP Form 5129 is used for compliance with currency reporting requirements, supplemental immigration documentation, agricultural quarantine matters, and the importation of merchandise by crew members who complete the individual declaration. This form is authorized by 19 U.S.C. 1431 and provided for by 19 CFR 4.7, 4.81, 122.44, 122.46, 122.83, 122.84 and 148.61–148.67. CBP Form 5129 is accessible at *http://www.cbp.gov/sites/default/files/documents/CBP%20Form%205129.pdf.*

Current Actions: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to CBP Form 5129.

Type of Review: Extension (without change).

Affected Public: Businesses.

Estimated Number of Respondents: 6,000,000.

Estimated Number of Total Annual Responses: 6,000,000.

Estimated Time per Response: 10 minutes.

Estimated Total Annual Burden Hours: 996,000.

Dated: November 17, 2014.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2014–27575 Filed 11–20–14; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0020]

Agency Information Collection Activities: Crew's Effects Declaration

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 60-Day Notice and request for comments; extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Crew's Effects Declaration (CBP Form 1304). CBP is proposing that this information collection be extended with no change to the burden hours or to the information collected. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before January 20, 2015 to be assured of consideration.

ADDRESSES: Direct all written comments to U.S. Customs and Border Protection, Attn: Tracey Denning, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229–1177, at 202–325–0265.

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13; 44 U.S.C. 3507). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden including the use of automated collection techniques or the use of other forms of information

technology; and (e) the annual cost burden to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

Title: Crew's Effects Declaration.

OMB Number: 1651–0020.

Form Number: Form 1304.

Abstract: CBP Form 1304, *Crew's Effects Declaration,* was developed through an agreement by the United Nations' Intergovernmental Maritime Consultative Organization (IMCO) in conjunction with the United States and various other countries. The form is used as part of the entrance and clearance of vessels pursuant to the provisions of 19 CFR 4.7 and 4.7a, 19 U.S.C. 1431, and 19 U.S.C. 1434. CBP Form 1304 is completed by the master of the arriving carrier to record and list the crew's effects that are onboard the vessel. This form is accessible at *http://forms.cbp.gov/pdf/CBP_Form_1304.pdf.*

Current Actions: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to CBP Form 1304.

Type of Review: Extension (without change).

Affected Public: Businesses.

Estimated Number of Respondents: 9,000.

Estimated Number of Total Annual Responses: 206,100.

Estimated Time per Response: 60 minutes.

Estimated Total Annual Burden Hours: 206,100.

Dated: November 17, 2014.

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2014–27574 Filed 11–20–14; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5756–N–42]

60-Day Notice of Proposed Information Collection: Application for Fee or Roster Personnel (Appraisers and Inspectors) Designation and Appraisal Reports

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* January 20, 2015.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Elissa Saunders, Acting Director, Office of Single Family Program Development, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Elissa Saunders at *Elssa.Saunders@hud.gov* or telephone 202–402–4308. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Application for Fee or Roster Personnel (Appraisers and Inspectors) Designation and Appraisal Reports.

OMB Approval Number: 2502–0538.

Type of Request: Extension.

Form Numbers: HUD 92563A, HUD 92563I, HUD 92564–CN Fannie Mae Forms: 1004, 1004c, 1025, 1073, 1075, 2055 and 1004MC.

1. *Description of the need for the information and proposed use:* Accurate and thorough appraisal reporting is critical to the accuracy of underwriting for the mortgage insurance process. The need for accuracy is increased for FHA insured mortgages since buyers tend to have more limited income and lower equity in the properties. This collection of information provides a more thorough and complete appraisal of prospective HUD-insured single-family properties ensuring that mortgages are acceptable for FHA insurance and thereby protect the interest of HUD, the taxpayers, and the FHA insurance fund. The collection allows HUD to maintain an effective appraisal program with the ability to discipline appraisers and inform potential homeowners of the benefits of purchasing an independent home inspection.

Respondents: Business or other for profit.

Estimated Number of Respondents: 17,162.

Estimated Number of Responses: 467,162.

Frequency of Response: On occasion.

Average Hours per Response: .05.

Total Estimated Burdens: 24,783.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: November 14, 2014.

Laura M. Marin,

Associate General Deputy Assistant Secretary for Housing-Associate Deputy Federal Housing Commissioner.

[FR Doc. 2014–27675 Filed 11–20–14; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5750–N–47]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Juanita Perry, Department of Housing and Urban Development, 451 Seventh Street SW., Room 7266, Washington, DC 20410; telephone (202) 402–3970; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, and suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Ms. Theresa M. Ritta, Chief Real Property Branch, the Department of Health and Human Services, Room 5B–17, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–6672 (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Ann Marie Oliva at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (i.e., acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: GSA: Mr. Flavio Peres, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street NW., Room 7040, Washington, DC 20405, (202) 501–0084; (This is not a toll-free number).

Dated: November 13, 2014.

Brian P. Fitzmaurice,

Director, Division of Community Assistance, Office of Special Needs Assistance Programs.

TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 11/21/2014

Suitable/Unavailable Properties

Building

Alaska

Commercial Lot w/2 Story Structure, Legends Parcel
412 Washington Ave.
Seward AK 99664
Landholding Agency: GSA
Property Number: 54201320010
Status: Surplus
GSA Number: 9–I–AK–0803AB
Directions: GSA is the disposal agency; NPD/DOII is the landholding agency
Comments: 3,538 sf.; restaurant.

Idaho

Ditchrider House
3970 1st Lane East
Parma ID 83660
Landholding Agency: GSA
Property Number: 54201420011
Status: Excess
GSA Number: 9–I–ID–0585
Directions: Landholding Agency: Dept. of Homeland Security; Disposal Agency: GSA
Comments: 1,194 sq. ft.; residence; 48+ months vacant; extensive repairs needed; contact GSA for more info.

BOR Upper Snake River Field Office
1359 Hansen Ave.
Burley ID 83318
Landholding Agency: GSA
Property Number: 54201420012
Status: Excess
GSA Number: 9–I–ID–0586
Directions: Landholding Agency: Interior; Disposal Agency: GSA
Comments: 9,828 sq. ft.; office; 48+ months vacant; good to moderate conditions; contact GSA for more info.

Illinois

Peoria Radio Repeater Site
Between Spring Creek and Caterpillar Lane
Peoria IL
Landholding Agency: GSA
Property Number: 54201420008
Status: Excess
GSA Number: I–D–IL–806
Directions: Landholding Agency; COE; Disposal agency GSA
Comments: 8x12 equipment storage shed; fair conditions contact GSA for more information.

Kansas

Former SS Admin. Building
801 S. Broadway
Pittsburg KS 66762
Landholding Agency: GSA
Property Number: 54201420007
Status: Surplus
GSA Number: 7–G–KS–0529
Comments: 5,918 sq. ft.; sits on .52 acres; Admin. bldg.; 42+ yrs.-old; fair conditions;

asbestos; lead-based paint; mold possible; contact GSA for more information.

Maryland

Carroll County Memorial USA RC
404 Malcolm Drive
Westminster MD 21157
Landholding Agency: GSA
Property Number: 54201430003
Status: Excess
GSA Number: 4–DMD–1130AA
Directions: Landholding agency; Army; Disposal Agency; GSA
Comments: 3 Building totaling 15,719 sq. ft., storage/maintenance good conditions; asbestos/lead-based paint/polychlorinated biphenyl; remediation required; contact GSA for more information.

Michigan

Nat'l Weather Svc Ofc
214 West 14th Ave.
Sault Ste. Marie MI
Landholding Agency: GSA
Property Number: 54200120010
Status: Excess
GSA Number: 1–C–MI–802
Comments: 2230 sq. ft., presence of asbestos, most recent use—office.

Texas

2 Buildings; Natural Resource Conservation Service Waco Facility
200 South Price Street
Waco TX 76501
Landholding Agency: GSA
Property Number: 54201430007
Status: Surplus
GSA Number: 7–A–TX–0556
Directions: Landholding agency; Agriculture; Disposal Agency; GSA.
Comments: 18,460 sq. ft.; storage; 60+ months vacant; very poor condition; within a security fence; contact GSA for more information.

Virginia

Johnson House and Shed
12503 Cavalry Court
Spotsylvania VA 22553
Landholding Agency: GSA
Property Number: 54201430005
Status: Excess
GSA Number: 4–I–VA–1145AA
Directions: Landholding Agency; Interior; Disposal Agency; GSA
Comments: Off-site removal only; 1,357 +/− sq. ft.; repairs needed; contact GSA for more information.

Washington

Old Colville Border Patrol
209 E. Juniper Ave.
Colville WA 99114
Landholding Agency: GSA
Property Number: 54201420009
Status: Excess
GSA Number: 9–Z–WA–1272
Directions: Landholding Agency: Dept. of Homeland Security; Disposal Agency: GSA
Comments: 5,500 sq. ft.; office; 18+ months vacant; good to moderate conditions; contact GSA for more info.

Old Oroville Border Patrol Station
1105 Main St.
Oroville WA 98844
Landholding Agency: GSA
Property Number: 54201420010
Status: Excess
GSA Number: 9–Z–WA–1272–AB
Directions: Landholding Agency: Dept. of Homeland Security; Disposal Agency: GSA
Comments: 5,500 sq. ft.; office; 18+ months vacant; good to moderate conditions; contact GSA for more info.

Wisconsin

St. Croix National Scenic Riverway Residential Structures
401 N. Hamilton St.
St. Croix Falls WI 54204
Landholding Agency: GSA
Property Number: 54201430001
Status: Excess
GSA Number: 1–I–WI–541B
Directions: Landholding Agency: Interior; Disposal Agency: GSA
Comments: House #1: 1,048 sq. ft.; House #2: 2,376 sq. ft.; House #3: 2,936 sq. ft.; good to fair conditions; LBP; contact GSA for more information.

Land

Missouri

Former Nike Battery Site
Kansas City 30
15616 S KK Highway
Pleasant Hill MO 64080
Landholding Agency: GSA
Property Number: 54201430002
Status: Surplus
GSA Number: 7–D–MO–0522
Comments: 19.52 acres +/− and 4.02 easement acres +/−; education use; contact GCA for more information.

South Carolina

Former FAA Outer Marker Facility—Greer
Brookfield Parkway
Greer SC 29651
Landholding Agency: GSA
Property Number: 54201410011
Status: Excess
GSA Number: 1–U–SC–0631
Comments: 0.99 acres; contact GSA for more information.

Tennessee

Former FAA Outer Marker Facility—Nashville
W End of Kinhawk Drive
Nashville TN 37211
Landholding Agency: GSA
Property Number: 54201410012
Status: Excess
GSA Number: 1–U–TN–0672
Comments: 12.20 acres; contact GSA for more information.

[FR Doc. 2014–27321 Filed 11–20–14; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R5–R–2014–N199; BAC–4311–K9–S3]

Great Swamp National Wildlife Refuge, Morris County, New Jersey; Final Comprehensive Conservation Plan and Finding of No Significant Impact

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability of the final comprehensive conservation plan (CCP) and finding of no significant impact (FONSI) for Great Swamp National Wildlife Refuge (NWR), located in Morris County, New Jersey, for public review and comment. In this final CCP, we describe how we will manage the refuge for the next 15 years.

ADDRESSES: You may view or obtain copies of the final CCP and FONSI by any of the following methods. You may request a hard copy or a CD–ROM.

Agency Web site: Download a copy of the document at *http://www.fws.gov/refuge/Great_Swamp/what_we_do/conservation.html.*

Email: Send requests to *northeastplanning@fws.gov.* Include ''Great Swamp CCP'' in the subject line of your email.

Mail: Bill Perry, Natural Resource Planner, U.S. Fish and Wildlife Service, 300 Westgate Center Drive, Hadley, MA 01035.

Fax: Attention: Bill Perry, 413–253–8468.

In-Person Viewing or Pickup: Call 973–425–1222 to make an appointment (necessary for view/pickup only) during regular business hours at Great Swamp NWR, 241 Pleasant Plains Road, Basking Ridge, NJ 07920. For more information on locations for viewing or obtaining documents, see ''Public Availability of Documents'' under **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Steven Henry, Acting Refuge Manager, 973–425–1222 (phone), or Bill Perry, Planning Team Leader, 413–253–8688 (phone); *northeastplanning@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

Introduction

With this notice, we finalize the CCP process for Great Swamp NWR. We started this process through a notice in the **Federal Register** (75 FR 41879) on July 19, 2010.

Great Swamp NWR was established by an act of Congress on November 3, 1960, and formally dedicated in 1964, primarily under the authorities of the Migratory Bird Treaty Act of 1918 (16 U.S.C. 703–711) and the Migratory Bird Conservation Act of 1929 (U.S.C. 715–715s, 45 Stat. 1222) as amended, ''for use as an inviolate sanctuary, or for any other management purpose, for migratory birds.'' The refuge currently encompasses 7,768 acres and has an approved acquisition boundary that

would allow for refuge expansion to a maximum of 9,429 acres. Great Swamp NWR is located approximately 26 miles from New York City and is an area that is heavily suburbanized. The refuge provides vital brooding, nesting, feeding, and resting habitat for a variety of migratory bird species, including waterfowl. Although established primarily for migratory birds, the refuge's mosaic of forested wetlands, emergent wetlands, and various successional stages of upland vegetation provides habitats for a diversity of wildlife species.

We announce our decision and the availability of the FONSI for the final CCP for Great Swamp NWR in accordance with National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*) requirements. We completed a thorough analysis of impacts on the human environment, which we included in the draft CCP/environmental assessment (EA).

The CCP will guide us in managing and administering Great Swamp NWR for the next 15 years. Alternative B, as described for the refuge in the draft CCP/EA, and with minor modifications described below, is the foundation for the final CCP.

Background

The National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd–668ee) (Refuge Administration Act), as amended by the National Wildlife Refuge System Improvement Act of 1997, requires us to develop a CCP for each refuge. The purpose for developing a CCP is to provide refuge managers with a 15-year plan for achieving refuge purposes and contributing to the mission of the National Wildlife Refuge System (NWRS), consistent with sound principles of fish and wildlife management, conservation, legal mandates, and our policies. In addition to outlining broad management direction on conserving wildlife and their habitats, CCPs identify wildlife-dependent recreational opportunities available to the public, including opportunities for hunting, fishing, wildlife observation and photography, and environmental education and interpretation. We will review and update the CCP at least every 15 years in accordance with the Refuge Administration Act.

CCP Alternatives, Including the Selected Alternative

Our draft CCP/EA (79 FR 27634) addressed several key issues, including:

- Evaluation of consolidating managed habitats of the refuge.
- Better understanding the implications and trade-offs of habitat management on refuge wildlife.
- Identifying and addressing climate change concerns impacting the refuge.
- Providing more public use opportunities on the refuge and linking to nearby urban populations.
- Providing additional hunting opportunities, including fall archery deer hunting and spring turkey hunting.
- Expanding and strengthening partnerships.

To address these issues and develop a plan based on the refuge's establishing purposes, vision, and goals, we evaluated four management alternatives for Great Swamp NWR in the draft CCP/EA. The alternatives have several actions in common. All alternatives include measures to control invasive species, monitor and abate diseases affecting wildlife and plant health, protect cultural resources, continue existing projects managed by outside programs, and manage threatened and endangered species populations on the refuge. There are other actions that differ among the alternatives. The draft CCP/EA provides a full description of each alternative and relates each to the issues and concerns that arose during the planning process. Below, we provide summaries of the four alternatives.

Management Alternatives

Alternative A (Current Management)

Alternative A (current management) satisfies the NEPA (40 CFR 1506.6(b)) requirement of a ''no action'' alternative, which we define as ''continuing current management.'' It describes our existing management priorities and activities, and serves as a baseline for comparing and contrasting alternatives B, C, and D. It would maintain our present levels of approved refuge staffing and the biological and visitor programs now in place. We would continue to manage for and maintain a diversity of habitats, including freshwater wetlands, impoundments, scrub-shrub, grasslands, wet meadows, and forests on the refuge. The refuge would continue to provide an active visitor use program that supports environmental education and interpretation, hunting, fishing, and wildlife observation and photography.

Alternative B (Enhance Biological Diversity and Public Use Opportunities)

This alternative is the Service-preferred alternative. It combines the actions we believe would most effectively achieve the refuge's purposes, vision, and goals, and respond to the issues raised during the scoping period. This alternative emphasizes management of specific refuge habitats to support viable populations of focal species whose habitat needs benefit other species, especially those of conservation concern. We would continue to maintain a diversity of forest, non-forested, open water, grassland, and scrub-shrub habitats. However, habitats would be reconfigured and maintained to create large (greater than 50 acres) contiguous patches to promote wildlife use, increase connectivity, decrease fragmentation, and increase maintenance efficiency and reduce associated costs. This alternative emphasizes habitat for priority bird species and federally listed species, including the bog turtle and Indiana bat.

This alternative would also enhance the refuge's public use opportunities, and place more emphasis on connecting with communities in nearby urban areas. It would expand the hunt program by pursuing the processes for permitting archery for deer and opening the refuge to turkey hunting. It would also improve wildlife viewing and photography opportunities in a variety of habitats, expand visitor center hours, and increase the number of environmental education and interpretation programs on- and off-refuge. It attempts to balance public use with resource protection.

Alternative C (Emphasis on Maximizing Natural Regeneration)

Alternative C emphasizes allowing natural succession or regeneration to occur to the maximum extent practical. We would maximize core forest habitats while maintaining large (i.e., greater than 50 acres) contiguous patches of actively managed grasslands and scrub-shrub habitats. This alternative would guide management to restore, where practical, the distribution of natural communities of the Great Swamp that would have resulted from natural processes without the influence of human settlement or management intervention. This alternative recognizes that refuge habitats and wildlife populations are not ecologically independent from the surrounding landscape, and that by taking a long-term regional perspective, the refuge can best contribute to higher conservation priorities at greater scales. This alternative continues to provide actively managed habitats in select areas to maintain wildlife viewing and photography opportunities for refuge visitors, as well as vital habitat for the refuge's species of conservation concern. Although some open water habitat would be eliminated, the refuge

would continue to maintain open water habitat for waterfowl use. Under this alternative, the public use program would be similar to alternative A; however, under this alternative, we would eliminate less used or dead-end trails in the wilderness area.

Alternative D (Focus on Expansion of Priority Public Uses)

Alternative D emphasizes expanding wildlife-dependent priority public uses on the refuge. Public use and access would be maximized to the greatest extent practical, while minimizing impacts to wildlife. We would expand refuge infrastructure, including construction of new trails, observation towers, signage, and parking lots; expand hunting; and allow fishing in select areas of the refuge. This alternative would maximize public outreach, enhance and develop new environmental interpretation and education programs, aggressively expand partnerships, and increase staff presence at programs and events. In general, refuge habitats would be managed similarly to alternative B; however, this alternative would increase open water habitat to improve public viewing opportunities.

Comments

We solicited comments on the draft CCP/EA from May 14 to June 30, 2014 (79 FR 27634). During the comment period, we received 80 written responses. We evaluated all of the substantive comments we received, and include a summary of those comments, and our responses to them, as appendix G in the final CCP.

Selected Alternative

After considering the comments we received on our draft CCP/EA, we made minor changes to alternative B, including not moving forward on the proposed parking area and wildlife observation opportunity on White Bridge Road, and correcting minor editorial, formatting, and typographical errors. These changes are described in the FONSI (appendix E in the final CCP) and in our response to public comments (appendix G in the final CCP).

We have selected alternative B to implement for Great Swamp NWR, with these minor changes, for several reasons. Alternative B comprises a mix of actions that, in our professional judgment, work best towards achieving the refuge's purposes, vision, and goals, NWRS policies, and the goals of other State and Regional conservation plans. We also believe that alternative B most effectively addresses key issues raised during the planning process. The basis of our decision is detailed in the FONSI (appendix E in the final CCP).

Public Availability of Documents

You can view or obtain the final CCP, including the FONSI, as indicated under **ADDRESSES**.

Dated: October 6, 2014.

Deborah Rocque,

Acting Regional Director, Northeast Region.

[FR Doc. 2014–27590 Filed 11–20–14; 8:45 a.m.]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[AAK6006201 134A2100DD AOR3B30.999900]

Intent To Prepare a Programmatic Environmental Impact Statement for the Proposed Integrated Resource Management Plan for the Colville Reservation in Okanogan and Ferry Counties, WA

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice advises the public that the Bureau of Indian Affairs (BIA), in cooperation with the Confederated Tribes of the Colville Reservation (Tribes), intends to gather information necessary to prepare a programmatic environmental impact statement (Programmatic EIS) for the proposed Integrated Resource Management Plan (IRMP) for the Colville Reservation in Okanogan and Ferry Counties, Washington. This notice also announces public scoping meetings to identify potential issues and content for inclusion in the Programmatic EIS.

DATES: The dates and locations of public scoping meetings will be published in the Omak-Okanogan County Chronicle, the Statesman Examiner, the Star, and the Tribal Tribune. Additional information will also be posted at the Tribes' Web site: *www.colvilletribes.com.* Written comments must arrive within 30 days following the public scoping meetings.

ADDRESSES: Comments may be submitted by mail, email, hand carry or fax to: Dr. BJ Howerton, Environmental Services Manager, BIA Northwest Regional Office, 911 NE 11th Avenue, Portland, OR 97232–4169, Phone: (503) 231–6749, Fax: (503) 231–2275, Email: *bj.howerton@bia.gov;* or Debra Wulff, BIA Superintendent, Colville Agency, Bureau of Indian Affairs, P.O. Box 111, Nespelem, WA 99155–0111, Phone: (509) 634–2316, Fax: (509) 634–2355, Email: *debra.wulff@bia.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. BJ Howerton at (503) 231–6749 or *bj.howerton@bia.gov* or Debra Wulff at (509) 634–2316 or *debra.wulff@bia.gov.*

SUPPLEMENTARY INFORMATION: The proposed action is the preparation of an IRMP for the Colville Reservation and the BIA approval of long-term natural resource planning goals and objectives for the Colville Reservation. The Tribes may use the Programmatic EIS for tiered, project-specific environmental assessments to cover specific actions as the IRMP is implemented.

The Tribes have managed their natural resources under the goals and objectives of an IRMP from 2000 to 2014. The new IRMP will replace the expiring plan. The Programmatic EIS will consider a proposed strategy in the IRMP that enhances the existing plan, where timber harvesting and livestock grazing levels remain at the existing levels with improved scheduling based on more accurate mapping data, open ground modeling and current forest inventory data. The strategy would include improved management practices to reduce erosion from forest roads, increase enforcement of livestock rotation requirements, and provide a formal project review process to ensure compliance with the IRMP and tribal resource codes.

Other alternative forest management strategies to be considered include: (1) A forest restoration strategy to emphasize thinning through the forest to return to historic conditions with a reduced harvest level, (2) an accelerated harvest strategy intended to maximize revenue to the Tribes, and (3) a No Forest Management strategy that would end timber harvesting.

Rangeland management alternatives include: (1) A strategy to rest and rotate range units on a yearly basis, (2) a strategy to increase livestock grazing by allowing additional grazing by off-reservation cattle ranchers, and (3) a strategy to eliminate livestock grazing altogether.

No Action or continuation of the current IRMP goals and objectives will also be considered along with any additional strategies or alternatives that may be developed as a result of public scoping.

Significant issues to be covered during the scoping process may include, but will not be limited to air quality, geology and soils, surface and groundwater resources, wildlife habitat, threatened and endangered species, cultural resources, socioeconomic conditions, land use, aesthetics, and Indian trust resources.

Directions for Submitting Public Comments

Please include your name, return address, and the caption ''Programmatic EIS, Colville Reservation IRMP'' on the first page of any written comments you submit. You may also submit comments at the public scoping meetings.

The public scoping meetings will be held to seek comments from the Tribal Business Council, resource managers, agency representatives, and community members concerning the planning and environmental issues surrounding the use of natural resources of the Colville Reservation. The meetings will be held at various Colville Reservation communities and notices will be published in Omak-Okanogan County Chronicle, the Statesman Examiner, the Star, and the Tribal Tribune. Additional information will also be posted at the Tribe's Web site: *www.colvilletribes.com.*

Public Availability of Comments

Comments, including names and addresses of respondents, will be available for public review at the BIA address shown in the **ADDRESSES** section of this notice, during regular business hours, Monday through Friday, except holidays. 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

This notice is published in accordance with sections 1503.1 of the Council on Environmental Quality Regulations (40 CFR parts 1500 through 1508) and Sec. 46.305 of the Department of the Interior Regulations (43 CFR Part 46), implementing the procedural requirements of NEPA, as amended (42 U.S.C. 4321 *et seq.*), and is in the exercise of authority delegated to the Assistant Secretary—Indian Affairs, by part 209 of the Departmental Manual.

Dated: November 10, 2014.

Kevin Washburn,

Assistant Secretary—Indian Affairs.

[FR Doc. 2014–27682 Filed 11–20–14; 8:45 am]

BILLING CODE 4310–W7–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[AAK6006201 145A2100DD AOR3030.999900]

Notice of Intent To Prepare an Environmental Impact Statement for Aiya Solar Project on the Moapa River Indian Reservation, Clark County, NV

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: In order to comply with the National Environmental Policy Act (NEPA), the Bureau of Indian Affairs (BIA), as lead agency in cooperation with the Moapa Band of Paiute Indians (Moapa Band), the Bureau of Land Management (BLM), and other Federal agencies, intend to prepare an environmental impact statement (EIS) that will evaluate a photovoltaic solar energy generation project on the Moapa River Indian Reservation and a transmission line located on tribal lands, private lands and Federal lands administered and managed by BLM in Clark County, Nevada.

This notice announces the beginning of the scoping process to solicit public comments and identify potential issues related to the EIS. It also announces that two public scoping meetings will be held in Nevada to identify potential issues, alternatives, and mitigation to be considered in the EIS.

DATES: The dates and locations of the public scoping meetings will be published in the Las Vegas Sun, Las Vegas Review-Journal, and Moapa Valley Progress 15 days before the scoping meetings. Written comments on the scope of the EIS or implementation of the proposal must arrive by December 22, 2014.

ADDRESSES: You may mail, email, or hand carry written comments to either Mr. Paul Schlafly, Natural Resource Specialist, Bureau of Indian Affairs, Southern Paiute Agency, 180 North 200 East Suite 111, P.O. Box 720, St. George, Utah 84770; telephone: (435) 674–9720; email: *paul.schlafly@bia.gov,* or Mr. Chip Lewis, Acting Regional Environmental Compliance Officer, BIA Western Regional Office, 2600 North Central Avenue, 4th Floor Mailroom, Phoenix, Arizona 85004; telephone: (602) 379–6782; email: *chip.lewis@bia.gov.*

SUPPLEMENTARY INFORMATION: The proposed Federal action, taken under 25 U.S.C. 415, is BIA's approval of a solar energy ground lease and associated agreements entered into by the Moapa Band with a subsidiary of First Solar, Inc. (First Solar) to provide for construction and operation of an up-to 100 megawatt (MW) alternating current solar photovoltaic (PV) electricity generation facility located entirely on the Moapa River Indian Reservation and specifically on lands held in trust by BIA for the Moapa Band. The proposed 230 kilovolt (kV) generation-tie transmission line required for interconnection may be located on Tribal lands, private lands and/or Federal lands administered and managed by BLM. First Solar has accordingly requested that the BIA and BLM additionally approve right-of-ways (ROWs) authorizing the construction and operation of the transmission line. Together, the proposed solar energy facility, transmission line, and other associated facilities will make up the proposed Moapa River Solar Project (Project).

The Project would be located in Township 14 South, Range 66 East, Sections 29, 30, 31, and 32 Mount Diablo Meridian, Nevada. The generation facility would generate electricity using First Solar's PV panels. Also included would be inverters, a collection system, an on-site substation to step-up the voltage to transmission-level voltage at 230 kV, an operations and maintenance building, and other related facilities. A single overhead 230 kV generation-tie transmission line, approximately 1.5 to 3 miles long, would connect the solar project to either NV Energy's Reid-Gardner 230kV substation or the proposed Reid Gardner Collector Substation, which is under development by NV Energy.

Construction of the Project is expected to take approximately 12 to 15 months. First Solar is expected to operate the energy facility for 30 years, with two options to renew the lease for an additional 10 years, if mutually acceptable to the Moapa Tribe and First Solar. The Project is expected to be built in one phase of up to 100 MW, per the demand of potential off-takers or utilities. During construction, the PV panels will be placed on top of fixed-tilt and/or single-axis tracking mounting systems that are set on steel posts embedded in the ground. Other foundation design techniques may be used depending on the site topography and conditions. No water will be used to generate electricity during operations. Water will be needed during construction for dust control and a minimal amount will be needed during operations for landscape irrigation and administrative and sanitary water use on site. The water supply required for the Project would be leased from the

Moapa Band and the EIS will consider the impacts of alternative sources and delivery methods.

The purposes of the Project are to: (1) Help to provide a long-term, diverse, and viable economic revenue base and job opportunities for the Moapa Band; (2) help Nevada and neighboring States to meet their State renewable energy needs; and (3) allow the Moapa Band, in partnership with First Solar, to optimize the use of the lease site while maximizing the potential economic benefit to the Tribe.

The BIA will prepare the EIS in cooperation with the Moapa Band, BLM, and possibly the Army Corps of Engineers, Environmental Protection Agency, and National Park Service. In addition, the U.S. Fish and Wildlife Service (USFWS) will provide input on the analysis. The resulting EIS will aim to: (1) Provide agency decision makers, the Moapa Band, and the general public with a comprehensive understanding of the impacts of the proposed Project and alternatives on the Reservation; (2) describe the cumulative impacts of increased development on the Reservation; and (3) identify and propose mitigation measures that would minimize or prevent significant adverse impacts. Consistent with these objectives, the EIS will analyze the proposed Project and appurtenant features, viable alternatives including other interconnection options, modified footprint alternatives, alternate routing for Project ROWs, and the No Action alternative. Other alternatives may be identified in response to issues raised during the scoping process.

The EIS will provide a framework for BIA and BLM to make determinations and to decide whether to take the aforementioned Federal actions. In addition, BIA will use and coordinate the NEPA commenting process to satisfy its obligations under Section 106 of the National Historic Preservation Act (16 U.S.C. 470f) as provided for in 36 CFR 800.2(d)(3). Tribal consultations will be conducted in accordance with policy, and tribal concerns will be given due consideration, including impacts on Indian trust assets. Other Federal agencies may rely on the EIS to make decisions under their authority and the Moapa Band may also use the EIS to make decisions under their Tribal Environmental Policy Ordinance. The USFWS will review the EIS for consistency with the Endangered Species Act, as amended, and other implementing acts, and may rely on the EIS to support its decisions and opinions regarding the Project.

Issues to be covered during the scoping process may include, but would not be limited to, Project impacts on: Air quality, geology and soils, surface and groundwater resources, biological resources, threatened and endangered species, cultural resources, socioeconomic conditions, land use, aesthetics, environmental justice, and Indian trust resources. In addition to those already identified above, Federal, State, and local agencies, along with other stakeholders that may be interested or affected by the BIA's decision on the proposed Project, are invited to participate in the scoping process.

Directions for Submitting Comments

Please include your name, return address, and the caption ''EIS, First Solar Solar Project,'' on the first page of any written comments. You may also submit comments at the public scoping meetings.

The public scoping meetings will be held to further describe the Project and identify potential issues and alternatives to be considered in the EIS. The first public scoping meeting will be held on the Reservation and the other public scoping meeting will be held in Las Vegas, Nevada. The dates of the public scoping meetings will be included in notices to be posted in the Las Vegas Sun, Las Vegas Review-Journal, and Moapa Valley Progress 15 days before the meetings.

Public Comment Availability

Comments, including names and addresses of respondents, will be available for public review at the mailing address shown in the **ADDRESSES** section during regular business hours, 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. 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.

Authority

This notice is published in accordance with 40 CFR 1501.7 of the Council of Environmental Quality regulations and 43 CFR 46.235 of the Department of the Interior Regulations implementing the procedural requirements of the NEPA (42 U.S.C. 4321 *et seq.*), and in accordance with the exercise of authority delegated to the Assistant Secretary—Indian Affairs by part 209 of the Department Manual.

Dated: November 14, 2014.

Kevin K. Washburn,

Assistant Secretary—Indian Affairs.

[FR Doc. 2014–27642 Filed 11–20–14; 8:45 am]

BILLING CODE 4310–W7–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNVS00560.L58530000.EU0000.241A.XXX; MO# 4500068492]

Notice of Realty Action: Non-Competitive Direct Sale of the Reversionary Interest in a Recreation and Public Purpose Act (R&PP) Patent, in Clark County, NV (N–90426)

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The reversionary interest held by the United States in a 5.22-acre parcel of public land is determined suitable for direct sale and release to the Paradise Bible Baptist Church, under the authority of the Federal Land Policy and Management Act, as amended. The purpose of the direct sale is to dispose of the reversionary interest clause in the patented lands, which represents certain restrictions and conditions that prevents the Paradise Bible Baptist Church from using the land for other purposes.

DATES: Interested parties may submit written comments regarding the direct sale and release of reversionary interest until January 5, 2015.

ADDRESSES: Send written comments to the Bureau of Land Management (BLM), Las Vegas Field Manager, 4701 N. Torrey Pines Drive, Las Vegas, Nevada 89130, or email: *ddickey@blm.gov.*

FOR FURTHER INFORMATION CONTACT: Dorothy Jean Dickey, 702–515–5119, or *ddickey@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: On February 5, 1998, a 5.22-acre parcel was patented (patent number 27–98–0017) to the Paradise Bible Baptist Church under the authority of the R&PP Act of June 14, 1926, as amended, 43 U.S.C. 869 *et seq.* The purpose for which the land can be used is restricted by a reversionary clause in the patent, which returns title to the United States if the tract is used for other purposes not provided for in

the patent. The purpose of the direct sale is to dispose of the reversionary interest in the patented lands which represents certain restrictions and conditions which prevents the Paradise Bible Baptist Church from using the land for other purposes.

The parcel proposed for direct sale of the reversionary interest is located east of Interstate Highway 15 on the corner of Emerson Avenue and Pacific Street in Las Vegas, Nevada, and is described as:

Mount Diablo Meridian, Nevada

T. 21 S., R. 61 E.,
Sec. 13, lot 20.
The area described contains 5.22 acres.

The purpose of the direct sale of the reversionary interest is so the land, patented to the Paradise Bible Baptist Church can be sold and/or used for other purposes. The Paradise Bible Baptist Church is planning on selling the church and moving to a new location. The R&PP Act reversionary clause in the patent requires the church be sold only to those qualified under the R&PP Act and be used only for the purposes allowed under the R&PP Act, or the patented land will revert back to the United States. The church cannot find a buyer who is interested in the land and who qualifies under the R&PP Act. A direct sale of the reversionary interest will allow the church to sell the property to any citizen or organization in the United States and to use the land for any purpose, without the threat of a reversion of the title for breach of patent conditions.

The proposed non-competitive direct sale of the reversionary interest is in conformance with the BLM Las Vegas Resource Management Plan (RMP) and the Record of Decision (ROD) approved on October 5, 1998. Authority for the sale and release of the reversionary interest is in conformance with Section 202 of the FLPMA Act of October 21, 1976, as amended, and Section 203, whereas the Secretary determines that the sale of the parcel meets the following disposal criteria. Such tract is difficult and uneconomic to manage because of its location or other characteristics—such as the subject's history of use, current level of development, and is neither required nor suitable for management by another Federal department or agency. This parcel of land is located in the urban setting of Las Vegas, Nevada, which is in a highly developed urban community that is surrounded by planned communities and commercial businesses; the church has experienced difficulty in attracting potential buyers because of the reversionary clause in patent 27–98–0017, issued on February 5, 1998.

The lands are being offered for sale using direct sale procedures pursuant to 43 CFR 2711.3–3. The reversionary interest in this land will be offered by direct sale and released to the Paradise Bible Baptist Church at the Fair Market Value (FMV) of $444,000.00 according to an appraisal report. The appraisal report is available for public review at the BLM Las Vegas Field Office at the address above.

Upon conveyance of the reversionary interest, the identified 5.22-acre parcel would no longer be subject to the reservations and conditions of the R&PP Act contained in Patent No. 27–98–0017 (unless otherwise noted below). All other terms and conditions of Patent No. 27–98–0017 will continue to apply. The release of the reversionary interest of the 5.22 acres will be made subject to the provisions of FLPMA, the applicable regulations of the Secretary of the Interior, all valid existing rights, and the following:

1. A right-of-way thereon for ditches or canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C. 945);

2. The terms and conditions of the United States Patent No. 27–98–0017, including but not limited to the reservation of all mineral deposits in the land so patented, and the right to prospect for, mine and remove such deposits from the same under applicable law and regulations to be established by the Secretary of the Interior;

3. Valid existing rights; and

4. An easement 30 feet in width along the north boundary and 50 feet in width along the east boundary of lot 20, section 13, T. 21 S., R. 61 E., M.D.M., Nevada, TOGETHER with a 25-foot spandrel area in the northeast corner thereof concave southwesterly and being tangent to the south line of said north 30 feet and tangent to the west line of said east 50 feet, in favor of Clark County, for road, public utilities, and flood control purposes to insure continued ingress and egress to adjacent lands.

The purchaser, by accepting the release of the reversionary interest of the United States agrees to indemnify, defend, and hold the United States, its officers, agents or employees harmless from any costs, damages, claims, causes of action, penalties, fines, liabilities, and judgments of any kind arising from the past, present or future acts or omissions of the purchaser, its employees, agents, contractors, or lessees, or third-party arising out of or in connection with the purchaser's acceptance of the aforementioned release or purchaser's use and/or occupancy of the land involved resulting in: (1) Violations of Federal, State, and local laws and regulations that are now, or in the future become, applicable to real property; (2) judgments, claims or demands of any kind assessed against the United States; (3) Cost, expenses, or damages of any kind incurred by the United States; (4) Releases or threatened releases of solid or hazardous waste(s) and/or hazardous substances(s), as defined by Federal or State environmental laws, off, on, into or under land, property, and other interests of the United States; (5) Other activities by which solids or hazardous substances or wastes, as defined by Federal and State environmental laws are generated, released, stored, used, or otherwise disposed of on the land involved, and any cleanup, response, remedial action or other actions related in any manner to said solid or hazardous substances or wastes; or (6) Natural resource damages as defined by Federal and State law. Patentee shall stipulate that it will be solely responsible for compliance with all applicable Federal, State, and local environmental and regulatory provisions, throughout the life of the facility, including any closure and/or post-closure requirements that may be imposed with respect to any physical plant and/or facility upon the land involved under any Federal, State, or local environmental laws or regulatory provisions. This covenant shall be construed as running with the land and may be enforced by the United States in a court of competent jurisdiction.

No warranty of any kind, express or implied, is given by the United States in connection with the sale or release of the reversionary interest. The documentation for land use conformance, National Environmental Policy Act procedures, a map, and the approved appraisal report covering the proposed sale, are available for review at the BLM Office located at the address listed above.

Interested parties may submit written comments on the direct sale of the reversionary interest for the subject 5.22-acre parcel. Comments on the direct sale are restricted to whether the land is physically suited for the proposal, whether the direct sale will maximize the future use or uses of the land, whether the direct sale is consistent with local planning and zoning, or if the direct sale is consistent with State and Federal programs. Interested parties may also submit written comments on whether the BLM followed proper administrative procedures in reaching the decision for

the direct sale of the reversionary interest.

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.

Any adverse comments will be reviewed by the BLM Nevada State Director, who may sustain, vacate, or modify this realty action. In the absence of any adverse comments, the decision will become effective on January 20, 2015. The reversionary interest will not be offered for sale and release until after the decision becomes effective.

Authority: 43 CFR 2711.1–2.

Vanessa L. Hice,

Assistant Field Manager, Las Vegas Field Office.

[FR Doc. 2014–27606 Filed 11–20–14; 8:45 am]

BILLING CODE 4310–HC–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–458 and 731–TA–1154 (Review)]

Certain Kitchen Appliance Shelving and Racks From China; Scheduling of Expedited Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of expedited reviews pursuant to section 751(c)(3) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(3)) (the Act) to determine whether revocation of the countervailing duty order and the antidumping duty order on certain kitchen appliance shelving and racks (''KASAR'') from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. For further information concerning the conduct of these reviews and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

DATES: Effective November 4, 2014.

FOR FURTHER INFORMATION CONTACT: Fred Ruggles (202–205–3187), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter 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 (*http://www.usitc.gov*). The public record for these reviews may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On Friday, November 4, 2014, the Commission determined that the domestic interested party group response to its notice of institution (79 FR 44862, August 1, 2014) of the subject five-year reviews was adequate and that the respondent interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting full reviews.[1] Accordingly, the Commission determined that it would conduct expedited reviews pursuant to section 751(c)(3) of the Act.

Staff report.—A staff report containing information concerning the subject matter of the reviews will be placed in the nonpublic record on Friday, November 28, 2014, and made available to persons on the Administrative Protective Order service list for these reviews. A public version will be issued thereafter, pursuant to section 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in section 207.62(d) of the Commission's rules, interested parties that are parties to the reviews and that have provided individually adequate responses to the notice of institution,[2] and any party other than an interested party to the reviews may file written comments with the Secretary on what determinations the Commission should reach in the reviews. Comments are due on or before Wednesday, December 3, 2014, and may not contain new factual information. Any person that is neither a party to the five-year reviews nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the reviews by Wednesday, December 3, 2014. However, should the Department of Commerce extend the time limit for its completion of the final results of its reviews, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. Please be aware that the Commission's rules with respect to filing have been amended. The amendments took effect on July 25, 2014. See 79 FR 35920 (June 25, 2014) and the revised Commission's Handbook on E-Filing, available on the Commission's Web site at *http://edis.usitc.gov.*

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the reviews must be served on all other parties to the reviews (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination: The Commission has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B) and 1675(c)(5)(C)(ii).

Authority: These reviews are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: November 17, 2014.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2014–27539 Filed 11–20–14; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–937]

Certain Windshield Wipers and Components Thereof Institution of Investigation Pursuant to 19 U.S.C. 1337

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S.

[1] A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and on the Commission's Web site.

[2] The Commission has found the responses submitted by Nashville Wire Products, Inc. and SSW Holding Company, Inc., U.S. producers of KASAR, to be individually adequate with respect to both their refrigeration shelving and their oven rack operations. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

International Trade Commission on October 15, 2014, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Valeo North America, Inc. of Troy, Michigan and Delmex de Juarez S. de R.L. de C.V. of Mexico. A letter supplementing the complaint was filed on October 29, 2014. 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 windshield wipers and components thereof by reason of infringement of certain claims of U.S. Patent No. 7,891,044 (''the '044 patent'') and U.S. Patent No. 7,937,798 (''the '798 patent''). The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2014).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on November 14, 2014, *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 windshield wipers and components thereof by reason of infringement of one or more of claims 1, 2, 5, 7, 8, 10–14, 18, 19, and 31–33 of the '044 patent and claims 1–12, 14, and 15 of the '798 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:

Valeo North America, Inc., 150 Stephenson Highway, Troy, MI 48083.

Delmex de Juarez S. de R.L. de C.V., Avenida de las Torres y calle Intermex #1681, Parque Industiral Intermex, Cd. Juarez, Chihuahua 32640, Mexico.

(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:

Trico Products Corporation, 3255 West Hamlin Road, Rochester Hills, Michigan 48309.

Trico Products, 1995 Billy Mitchell Boulevard, Brownsville, TX 78521.

Trico Componentes SA de CV, Ave Michigan #200, Matamoros, Tamaulipas, Mexico; and

(3) For the investigation so instituted, the Honorable Thomas B. Pender is designated as the presiding Administrative Law Judge.

The Commission has determined to assign this investigation to Judge Pender, who is the presiding Administrative Law Judge in Certain Windshield Wipers and Components Thereof, Inv. No. 337–TA–928, in view of the overlapping subject matter in the two investigations. The presiding Administrative Law Judge is authorized to consolidate Inv. No. 337–TA–928 and this investigation if he deems it appropriate.

The Office of Unfair Import Investigations 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(d)–(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: November 17, 2014.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2014–27560 Filed 11–20–14; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–14–039]

Government in the Sunshine Act Meeting Notice

AGENCY HOLDING THE MEETING: United States International Trade Commission

TIME AND DATE: November 26, 2014 at 9:30 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: none
2. Minutes
3. Ratification List
4. Vote in Inv. Nos. 701–TA–524–525 and 731–TA–1260–1261 (Preliminary) (Certain Welded Line Pipe from Korea and Turkey). The Commission is currently scheduled to complete and file its determinations on December 1, 2014; views of the Commission are currently scheduled to be completed and filed on December 8, 2014.
5. Outstanding action jackets: none.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

Issued: November 19, 2014.

By order of the Commission.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2014–27722 Filed 11–19–14; 4:15 pm]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1121–0269]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Reinstatement With Change of a Previously Approved Collection for Which Approval Has Expired; 2014 Census of Publicly Funded Forensic Crime Laboratories

AGENCY: Bureau of Justice Statistics, Office of Justice Programs, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the **Federal Register** at Volume 79, Number 179, pages 55503–55504, September 16, 2014, allowing for a 60 day comment period.

DATES: Comments are encouraged and will be accepted for additional days until December 22, 2014.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Matthew Durose, Statistician, Bureau of Justice Statistics, Office of Justice Programs, U.S. Department of Justice, 810 Seventh Street NW., Washington, DC 20531 (phone: 202–307–6119). 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 20530 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;

—Enhance the quality, utility, and clarity of the information to be collected; and/or

—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:* Reinstatement with change of a previously approved collection for which approval has expired.

2. *The Title of the Form/Collection:* 2014 Census of Publicly Funded Forensic Crime Laboratories.

3. *The agency form number:* The form number is CFCL–14, Bureau of Justice Statistics, Office of Justice Programs, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Respondents will represent federal, state, and local governments. The primary goals of the work under this clearance are to produce a national roster of publicly funded forensic crime laboratories operating in 2014 and to generate accurate and reliable information about their services and resources. A questionnaire will be directed to federal, state, and local crime labs that analyze physical evidence collected in criminal matters and provide court testimony on such evidence. The CPFFCL–14 will provide national statistics on laboratory personnel, budgets, workloads, forensic backlogs, and quality assurances (e.g., accreditations, proficiency testing, examiner certifications, and resources devoted to research). BJS will expand the scope of the CPFFCL–14 to capture additional information about an emerging forensic science discipline known as digital and multimedia evidence. BJS plans to publish this information in reports and reference it when responding to queries from the U.S. Congress, Executive Office of the President, the U.S. Supreme Court, state officials, international organizations, researchers, students, the media, and others interested in criminal justices statistics.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 510 respondents at 2.9 hours each. Respondents have the option to provide responses using either paper or web-based questionnaires. The burden estimate is based on feedback from respondents gathered during pilot testing.

6. *An estimate of the total public burden (in hours) associated with the collection:* There is an estimated 1,479 annual total burden hours associated with this collection.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: November 18, 2014.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2014–27597 Filed 11–20–14; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

[OMB Number 1140–0040]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Application for an Amended Federal Firearms License

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 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 is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 79, Number 180, page 55829 on September 17, 2014, allowing for a 60 day comment period.

DATES: The purpose of this notice is to allow for an additional 30 days for public comment until December 22, 2014.

FOR FURTHER INFORMATION CONTACT: If you have comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Tracey Robertson, Bureau of Alcohol, Tobacco, Firearms and Explosives, 244 Needy Road, Martinsburg, WV 25405. 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 send email to *OIRA_submission@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;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection 1140–0040

(1) *Type of Information Collection:* Extension of an existing collection.

(2) *Title of the Form/Collection:* Application for an Amended Federal Firearms License.

(3) *Agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: ATF Form 5300.38.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: Individual or households.

Abstract: The form is primarily used when a Federal firearms licensee makes application to change the location of the business premises. The form is also used for changes of trade or business name, changes of mailing address, changes of contact information, changes of hours of operation/availability, and allows for licensees to indicate any changes of business structure.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 18,000 respondents will take 30 minutes to complete the form.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 9,000 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3E.405B, Washington, DC 20530.

Dated: November 18, 2014.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2014–27595 Filed 11–20–14; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

[OMB Number 1140–0080]

Agency Information Collection Activities: Proposed eCollection eComments Requested; Notification of Change of Mailing or Premise Address

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 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 is published to obtain comments from the public and affected agencies. This proposed information collection was previously published in the **Federal Register** Volume 79, Number 180, page 55828 on September 17, 2014, allowing for a 60 day comment period.

DATES: The purpose of this notice is to allow for an additional 30 days for public comment until December 22, 2014.

FOR FURTHER INFORMATION CONTACT: If you have comments, especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Christopher Reeves, Bureau of Alcohol, Tobacco, Firearms and Explosives, 244 Needy Road, Martinsburg, WV 25405. 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 send email to *OIRA_submission@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;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection 1140–0080

(1) *Type of Information Collection:* Extension of an existing collection.

(2) *Title of the Form/Collection:* Notification of Change of Mailing or Premise Address.

(3) *Agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: None.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Not-for-profit institutions.
Other: Business or other for-profit.
Abstract: Licensees and permittees whose mailing address will change must notify the Chief, Federal Explosives Licensing Center, at least 10 days before the change. The information is used by ATF to identify correct locations of storage of explosives licensees/permittees and location of storage of explosive materials for purposes of inspection, as well as to notify permittees/licensees of any change in regulations or laws that may affect their business activities.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 1,000 respondents will take 10 minutes to 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 170 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3E.405B, Washington, DC 20530.

Dated: November 18, 2014.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2014–27596 Filed 11–20–14; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Documenting and Evaluating Initial Results of the Office of Disability Employment Policy's Getting to Work Curriculum

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Office of Disability Employment Policy (ODEP) sponsored information collection request (ICR) proposal titled, ''Documenting and Evaluating Initial Results of the Office of Disability Employment Policy's Getting to Work Curriculum,'' to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 et seq.). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before December 22, 2014.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201407-1230-001* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–ODEP, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks PRA authority for proposed information collections related to an evaluation that will document initial results of the Getting to Work Curriculum. More specifically, this ICR is to obtain OMB approval under to PRA to conduct (1) a survey of managers and counselors who work for housing providers funded by the U.S. Department of Housing and Urban Development (HUD) and (2) focus groups with staff at HUD-funded housing providers. This data collection will be used to evaluate *Getting to Work: a Training Curriculum for HIV/AIDS Service Providers and Housing Providers,* a 3-module online training produced by the ODEP and HUD.

This proposed information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. For additional information, see the related notice published in the **Federal Register** on September 2, 2014 (79 FR 52043).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register.** In order to help ensure appropriate consideration, comments should mention OMB ICR Reference Number 201407–1230–001. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–ODEP.
Title of Collection: Documenting and Evaluating Initial Results of the Office of Disability Employment Policy's Getting to Work Curriculum.
OMB ICR Reference Number: 201407–1230–001.
Affected Public: State, Local, and Tribal Governments.
Total Estimated Number of Respondents: 77.
Total Estimated Number of Responses: 1,072.
Total Estimated Annual Time Burden: 608 hours.
Total Estimated Annual Other Costs Burden: $0.

Dated: November 17, 2014.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2014–27566 Filed 11–20–14; 8:45 am]

BILLING CODE 4510–FK–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Alternative Method of Compliance for Certain Simplified Employee Pensions

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employee Benefits Security Administration (EBSA) sponsored information collection request (ICR) titled, ''Alternative Method of Compliance for Certain Simplified Employee Pensions,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before December 22, 2014.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201411-1210-001* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–EBSA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Alternative Method of Compliance for Certain Simplified Employee Pensions information collection. The alternative disclosure arrangement established through regulations 29 CFR 2520.104–49 relieves a sponsor of a non-model Simplified Employee Pension (SEP) of most Employee Retirement Income Security Act (ERISA) Title I reporting and disclosure requirements. In addition, disclosure requirements set forth in the regulation ensure an administrator of a non-model SEP provides participants with specific written information concerning the SEP. This information collection requirement generally requires timely written disclosure to employees eligible to participate in a non-model SEP, including specific information concerning: Participation requirements; allocation formulas for employer contributions; designated contact persons for further information; and, for employer recommended Individual Retirement Accounts (IRAs), specific IRA terms—such as rates of return and any restrictions on withdrawals. Moreover, general information is required that provides a clear explanation of the operation of the non-model SEP; participation requirements, and any withdrawal restrictions; and the tax treatment of the SEP-related IRA. Furthermore, statements must be provided to inform participants of: Any other IRAs under the non-model SEP other than that to which employer contributions are made; any options regarding rollovers and contributions to other IRAs; descriptions of U.S. Department of the Treasury, Internal Revenue Service disclosure requirements to participants and information regarding social security integration (if applicable); and timely notification of any amendments to the terms of the non-model SEP. ERISA section 110 authorizes this information collection. *See* 29 U.S.C. 1030.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1210–0034.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on December 31, 2014. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on May 21, 2014 (79 FR 29208).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register.** In order to help ensure appropriate consideration, comments should mention OMB Control Number 1210–0034. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–EBSA.

Title of Collection: Alternative Method of Compliance for Certain Simplified Employee Pensions.

OMB Control Number: 1210–0034.

Affected Public: Private Sector—Businesses or other for-profits.

Total Estimated Number of Respondents: 36,000.

Total Estimated Number of Responses: 68,000.

Total Estimated Annual Time Burden: 21,000 hours.

Total Estimated Annual Other Costs Burden: $25,000.

Dated: November 17, 2014.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2014–27567 Filed 11–20–14; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Respiratory Protection Standard

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Occupational Safety and Health Administration (OSHA) sponsored information collection request (ICR) titled, ''Respiratory Protection Standard,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 et seq. Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before December 22, 2014.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201405–1218–002* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OSHA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor—OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Respiratory Protection Standard information collection requirements codified in regulations 29 CFR 1910.134 that assist an employer in protecting the health of workers exposed to airborne contaminants, physical hazards, and biological agents. The Standard contains requirements for program administration; a written respirator-protection program with worksite-specific procedures; respirator selection; worker training; fit testing; medical evaluation; respirator use; respirator cleaning, maintenance, and repair; and other provisions. Occupational Safety and Health Act sections 2, 6, and 8 authorize this information collection. *See* 29 U.S.C. 651, 655, and 657.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1218–0099.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on January 31, 2015. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on July 10, 2014 (79 FR 39412).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1218–0099. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–OSHA.

Title of Collection: Respiratory Protection Standard.

OMB Control Number: 1218–0099.

Affected Public: Private Sector—businesses or other for-profits.

Total Estimated Number of Respondents: 610,213.

Total Estimated Number of Responses: 21,438,996.

Total Estimated Annual Time Burden: 6,642,537 hours.

Total Estimated Annual Other Costs Burden: $188,844,691.

Dated: November 17, 2014.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2014–27544 Filed 11–20–14; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Advisory Committee on Veterans' Employment, Training and Employer Outreach (ACVETEO): Meeting

AGENCY: Veterans' Employment and Training Service (VETS), Department of Labor.

ACTION: Notice of open meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the ACVETEO. The ACVETEO will discuss the VETS core programs and services regarding efforts that assist veterans seeking employment and raise employer awareness as to the advantages of hiring veterans. There will be an opportunity for persons or organizations to address the committee. Any individual or organization that wishes to do so should contact Mr. Timothy Green at 202–693–4723.

Individuals who will need accommodations for a disability in order to attend the meeting (e.g., interpreting services, assistive listening devices, and/or materials in alternative format) should notify the Advisory Committee no later than Friday, December 12, 2014 by contacting Mr. Gregory Green at 202–693–4734. Requests made after this date will be reviewed, but availability of the requested accommodations cannot be guaranteed. The meeting site is accessible to individuals with disabilities. This Notice also describes the functions of the ACVETEO. Notice of this meeting is required under Section 10(a)(2) of the Federal Advisory Committee Act. This document is intended to notify the general public.

Date and Time: Thursday, December 18, 2014 beginning at 9 a.m. and ending at approximately 4:00 p.m. (E.S.T.).

ADDRESSES: The meeting will take place at the U.S. Department of Labor, Frances Perkins Building, 200 Constitution Avenue NW., Washington, DC 20210, Suite N–3437C. Members of the public are encouraged to arrive early to allow for security clearance into the Frances Perkins Building.

Security Instructions: Meeting participants should use the visitors' entrance to access the Frances Perkins Building, one block north of Constitution Avenue at 3rd and C Streets NW. For security purposes meeting participants must:

1. Present a valid photo ID to receive a visitor badge.

2. Know the name of the event being attended: The meeting event is the Advisory Committee on Veterans' Employment, Training and Employer Outreach (ACVETEO).

3. Visitor badges are issued by the security officer at the Visitor Entrance located at 3rd and C Streets NW. When receiving a visitor badge, the security officer will retain the visitor's photo ID until the visitor badge is returned to the security desk.

4. Laptops and other electronic devices may be inspected and logged for identification purposes.

5. Due to limited parking options, Metro is the easiest way to access the Frances Perkins Building.

Notice of Intent To Attend the Meeting: All meeting participants are being asked to submit a notice of intent to attend by Friday, December 12, 2014, via email to Mr. Timothy Green at *green.timothy.a@dol.gov,* subject line ''December 2014 ACVETEO Meeting.''

FOR FURTHER INFORMATION CONTACT: Mr. Timothy Green, Designated Federal Official for the ACVETEO, (202) 693–4723.

SUPPLEMENTARY INFORMATION: The ACVETEO is a Congressionally mandated advisory committee authorized under Title 38, U.S. Code, Section 4110 and subject to the Federal Advisory Committee Act, 5 U.S.C. App. 2, as amended. The ACVETEO is responsible for: Assessing employment and training needs of veterans; determining the extent to which the programs and activities of the U.S. Department of Labor meet these needs; assisting to conduct outreach to employers seeking to hire veterans; making recommendations to the Secretary, through the Assistant Secretary of Labor for VETS, with respect to outreach activities and employment and training needs of Veterans; and carrying out such other activities necessary to make required reports and recommendations. The ACVETEO meets at least quarterly.

Agenda

9:00 a.m. Welcome and remarks, Keith Kelly, Assistant Secretary of Labor for Veterans' Employment and Training
9:05 a.m. Administrative Business, Timothy Green, Designated Federal Official
9:15 a.m. Discussion and work on Fiscal Year 2014 Report, J. Michael Haynie, ACVETEO Chairman
10:00 a.m. Break
10:15 a.m. Continued discussion and work on Fiscal Year 2014 Report, J. Michael Haynie, ACVETEO Chairman
11:00 a.m. Break
11:15 a.m. Continued discussion and work on Fiscal Year 2014 Report, J. Michael Haynie, ACVETEO Chairman
12:00 p.m. Lunch
1:00 p.m. Discussion on Fiscal Year 2015 issues
2:00 p.m. Break
2:15 p.m. Continued discussion on Fiscal Year 2015 issues
3:45 p.m. Public Forum, Timothy Green, Designated Federal Official
4:00 p.m. Adjourn

Signed in Washington, DC, this 17th day of November, 2014.

Keith Kelly,

Assistant Secretary of Labor for Veterans' Employment and Training.

[FR Doc. 2014–27625 Filed 11–20–14; 8:45 am]

BILLING CODE 4510–79–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–83,015]

Fenner Precision, Inc., Including On-Site Leased Workers From Aerotek Buffalo, New York; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on November 5, 2013, applicable to workers of Fenner Precision, Inc., Buffalo, New York. The Department's notice of determination was published in the **Federal Register** on November 26, 2013 (78 FR 70581–70583).

At the request of state workforce office, the Department reviewed the certification for workers of the subject firm. The workers were engaged in activities related to the production of polyurethane CAST products.

The company reports that workers leased from Aerotek were employed on-site at the Buffalo, New York location of Fenner Precision, Inc. The Department has determined that these workers were sufficiently under the control of the subject firm to be considered leased workers.

Based on these findings, the Department is amending this certification to include workers leased from Aerotek working on-site at the Buffalo, New York location of Fenner Precision, Inc.

The amended notice applicable to TA–W–83,015 is hereby issued as follows:

All workers of Fenner Precision, Inc, including on-site leased workers from Aerotek, Buffalo, New York, who became totally or partially separated from employment on or after August 21, 2012 through November 5, 2015, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for

adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2014–27617 Filed 11–20–14; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–82,557; TA–W–82,557A; TA–W–82,557B; TA–W–82,557C]

Ericsson Inc. Wireline Network OPS Building Maintenance and Engineering Group (BME) Including On-Site Leased Workers From J.M. Neil & Associates, Inc. Overland Park, Kansas; Ericsson Inc. Network Platforms Group Overland Park, Kansas; Ericsson Inc. Wireless Core Group Including On-Site Leased Workers From J.M. Neil & Associates, Inc., Apeiron, Convergenz LLC, and HL YOH Overland Park, Kansas; Ericsson Inc. National Coordination and Dispatch Center (NCDC) Including On-Site Leased Workers From HL YOH and Apex Atlanta, Georgia; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (''Act''), 19 U.S.C. 2273, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on April 2, 2013, applicable to workers of Ericsson Inc., Wireline Network Ops Building Maintenance and Engineering Group (BME), including on-site leased workers from J.M. Neil & Associates, Inc., Overland Park, Kansas (TA–W–82,557) and Ericsson Inc., Network Platforms Group, Overland Park, Kansas (TA–W–82,557A). The Department's Notice of Determination was published in the **Federal Register** on April 30, 2013 (Volume 78 FR Page 25305).

At the request of a state workforce office, the Department reviewed the certification for workers of the subject firm. Workers of Ericsson Inc., Wireline Network Ops Building Maintenance and Engineering Group (BME), including on-site leased workers from J.M. Neil & Associates, Inc., Overland Park, Kansas (TA–W–82,557) are engaged in activities related to the supply of management of network operations and related telecommunications operators, including proactive alarm monitoring of HVAC, power, building door, halon, and fire detection alarms. Workers of Ericsson Inc., Network Platforms Group, Overland Park, Kansas (TA–W–82,557A) are engaged in activities related management of network operations and related telecommunications operators including wireless and wireline network services such as ticket triage, testing, alarm response, monitoring, verification, and referral to local exchange carriers for routing trouble failures. Workers of Ericsson Inc., Wireless Core, including on-site leased workers from J.M. Neil & Associates, Inc., Apeiron, Convergenz LLC, and HL Yoh, Overland Park, Kansas (TA–W–82,557B) are engaged in activities related to the supply of technical support of wireless core network elements and routine break/fix and preventative maintenance activities. Workers of Ericsson Inc., National Coordination and Dispatch Center (NCDC), including on-site leased workers from HL Yoh and Apex, Atlanta, Georgia (TA–W–82,557C) are engaged in activities related to the supply of dispatched work orders to field technicians to build or fix the telecommunications network.

The investigation confirmed that worker separations in the Wireless Core Group and NCDC are attributable to the shift of services to a foreign country that was the basis for the original certification.

The amended notice applicable to TA–W–82,557 is hereby issued as follows:

All workers of Ericsson Inc., Wireline Network Ops Building Maintenance and Engineering Group (BME), including on-site leased workers from J.M. Neil & Associates, Inc., Overland Park, Kansas (TA–W–82,557), Ericsson Inc., Network Platforms Group, Overland Park, Kansas (TA–W–82,557A), Ericsson Inc., Wireless Core, including on-site leased workers from J.M. Neil & Associates, Inc., Apeiron, Convergenz LLC, and HL Yoh, Overland Park, Kansas (TA–W–82,557B) and Ericsson Inc., National Coordination and Dispatch Center (NCDC), including on-site leased workers from HL Yoh and Apex, Atlanta, Georgia (TA–W–82,557C) who became totally or partially separated from employment on or after March 12, 2012 through April 2, 2015, and all workers in the group threatened with total or partial separation from employment on the date of certification through two years from the date of certification, are eligible to apply for adjustment assistance under Chapter 2 of Title II of the Trade Act of 1974, as amended.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2014–27615 Filed 11–20–14; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than December 1, 2014.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than December 1, 2014.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room N–5428, 200 Constitution Avenue NW., Washington, DC 20210.

Signed at Washington, DC, this 13th day of November 2014.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

APPENDIX

[14 TAA petitions instituted between 11/3/14 and 11/7/14]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
85622	AFB International (Union)	O'Fallon, MO	11/03/14	10/30/14
85623	Republic Steel (Union)	Canton, OH	11/03/14	10/31/14
85624	VF Jeanswear Limited Partnership (Company)	Greensboro, NC	11/03/14	10/31/14
85625	Entergy Vermont Yankee (State/One-Stop)	Vernon, VT	11/03/14	10/29/14
85626	Air System Components (Company)	El Paso, TX	11/03/14	10/31/14
85627	Mary's River Lumber Company (State/One-Stop)	Montesano, WA	11/03/14	10/28/14
85628	Devro, Inc. (Company)	Swansea, SC	11/05/14	11/04/14
85629	Amgen (State/One-Stop)	Seattle and Bothell, WA	11/05/14	11/03/14
85630	General Dynamics Ordnance & Tactical Systems (Union)	Scranton, PA	11/06/14	11/04/14
85631	Greatbatch, Ltd. (Company)	Plymouth, MN	11/06/14	10/30/14
85632	Intuit, Inc (State/One-Stop)	Oakland, CA	11/07/14	11/06/14
85633	Nokia, Inc. (State/One-Stop)	Saint Louis, MT	11/07/14	11/06/14
85634	G&D, LLC d/b/a Lake Region Medical (formerly Accellent) (Company).	Arvada, CO	11/07/14	11/05/14
85635	United Technologies Aerospace Systems (UTAS) (Union)	Windsor Locks, CT	11/07/14	11/07/14

[FR Doc. 2014–27616 Filed 11–20–14; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 (''the Act'') and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to Section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than December 1, 2014.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than December 1, 2014.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, Room N–5428, 200 Constitution Avenue NW., Washington, DC 20210.

Signed at Washington, DC, this 30th day of October 2014.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

APPENDIX

[7 TAA petitions instituted between 10/27/14 and 10/31/14]

TA–W	Subject firm (petitioners)	Location	Date of institution	Date of petition
85615	Trane U.S. Inc., Tyler Operations/Residential Solutions (State/One-Stop).	Tyler, TX	10/27/14	10/24/14
85616	Luminus Devices, Inc. (Workers)	Billerica, MA	10/27/14	10/18/14
85617	Day & Zimmermann Kansas LLC (State/One-Stop)	Parsons, KS	10/28/14	10/27/14
85618	BSN Medical Inc. (Company)	Rutherford College, NC	10/29/14	10/23/14
85619	Oracle Corporation (Workers)	Morrisville, NC	10/29/14	10/28/14
85620	CPI Locus Microwave (Workers)	Boalsburg, PA	10/30/14	10/30/14
85621	Learjet (Company)	Wichita, KS	10/31/14	10/30/14

[FR Doc. 2014–27556 Filed 11–20–14; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) number and alternative trade adjustment assistance (ATAA) by (TA–W) number issued during the period of *November 3, 2014 through November 7, 2014.*

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Section (a)(2)(A) all of the following must be satisfied:

A. a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. the sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision; or

II. Section (a)(2)(B) both of the following must be satisfied:

A. a significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. there has been a shift in production by such workers' firm or subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. the country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States;

2. the country to which the workers' firm has shifted production of the articles to a beneficiary country under the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or

3. there has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

Also, in order for an affirmative determination to be made for secondarily affected workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) the workers' firm (or subdivision) is a supplier or downstream producer to a firm (or subdivision) that employed a group of workers who received a certification of eligibility to apply for trade adjustment assistance benefits and such supply or production is related to the article that was the basis for such certification; and

(3) either-

(A) the workers' firm is a supplier and the component parts it supplied for the firm (or subdivision) described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) a loss or business by the workers' firm with the firm (or subdivision) described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for the Division of Trade Adjustment Assistance to issue a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

1. Whether a significant number of workers in the workers' firm are 50 years of age or older.

2. Whether the workers in the workers' firm possess skills that are not easily transferable.

3. The competitive conditions within the workers' industry (i.e., conditions within the industry are adverse).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

None.

Affirmative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

85,570, Heritage Home Group (HHG), Conover, North Carolina, October 1, 2013.

85,588, Dominion Dealer Solutions, LLC., Norfolk, Virginia. October 9, 2013.

85,598, Arkwright Advanced Coating Inc., Fiskeville, Rhode Island. October 14, 2013.

85,604, Anchor Danly LLC, Kentwood, Michigan. October 3, 2013.

85,606, The Store Kraft Manufacturing Company, Beatrice, Nebraska. October 17, 2013.

85,631, Greatbatch, Ltd., Plymouth, Minnesota. October 30, 2013.

Negative Determinations for Alternative Trade Adjustment Assistance

In the following cases, it has been determined that the requirements of 246(a)(3)(A)(ii) have not been met for the reasons specified.

None.

Negative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

Because the workers of the firm are not eligible to apply for TAA, the workers cannot be certified eligible for ATAA.

The investigation revealed that criteria (a)(2)(A)(I.A.) and a)(2)(B)(II.A.) (employment decline) have not been met.

85,603, Eight Floor Promotions, Celina, Ohio.

The investigation revealed that criteria (a)(2)(A)(I.C.) (increased imports) and (a)(2)(B)(II.B.) (shift in production to a foreign country) have not been met.

85,419, Cinram Group Inc., Olyphant, Pennsylvania.

85,562, Unimin Corporation, Gleason, Tennessee.

85,575, AMFIRE Mining Company LLC, Portage, Pennsylvania.

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

85,245, Detroit Tool & Engineering, Inc., Lebanon, Missouri.

85,527, Syncreon Technology (America), Inc., Allentown, Pennsylvania.

85,545, Rural Metro Ambulance, Indianapolis, Indiana.

85,584, Wacom Technology, Corporation, Vancouver, Washington.

85,594, SuperValu, Inc., Boise, Idaho.

Determinations Terminating Investigations of Petitions for Worker Adjustment Assistance

After notice of the petitions was published in the **Federal Register** and on the Department's Web site, as required by Section 221 of the Act (19 U.S.C. 2271), the Department initiated investigations of these petitions.

The following determinations terminating investigations were issued because the petitioner has requested that the petition be withdrawn.

85,611, GrafTech International Holdings Inc., Parma, Ohio.

85,627, Mary's River Lumber Company, Montesano, Washington.

The following determinations terminating investigations were issued because the petitioning groups of workers are covered by active certifications. Consequently, further investigation in these cases would serve no purpose since the petitioning group of workers cannot be covered by more than one certification at a time.

85,578, Avery Dennison, Lenoir, North Carolina.

I hereby certify that the aforementioned determinations were issued during the period of *November 3, 2014 through November 7, 2014.* These determinations are available on the Department's Web site *www.tradeact/taa/taa_search_form.cfm* under the searchable listing of determinations or by calling the Office of Trade Adjustment Assistance toll free at 888–365–6822.

Signed at Washington, DC, this 13th day of November 2014.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2014–27614 Filed 11–20–14; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, as amended (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) number and alternative trade adjustment assistance (ATAA) by (TA–W) number issued during the period of *October 27, 2014 through October 31, 2014.*

In order for an affirmative determination to be made for workers of a primary firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(a) of the Act must be met.

I. Section (a)(2)(A) all of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. the sales or production, or both, of such firm or subdivision have decreased absolutely; and

C. increased imports of articles like or directly competitive with articles produced by such firm or subdivision have contributed importantly to such workers' separation or threat of separation and to the decline in sales or production of such firm or subdivision; or

II. Section (a)(2)(B) both of the following must be satisfied:

A. A significant number or proportion of the workers in such workers' firm, or an appropriate subdivision of the firm, have become totally or partially separated, or are threatened to become totally or partially separated;

B. there has been a shift in production by such workers' firm or subdivision to a foreign country of articles like or directly competitive with articles which are produced by such firm or subdivision; and

C. One of the following must be satisfied:

1. The country to which the workers' firm has shifted production of the articles is a party to a free trade agreement with the United States;

2. the country to which the workers' firm has shifted production of the articles to a beneficiary country under the Andean Trade Preference Act, African Growth and Opportunity Act, or the Caribbean Basin Economic Recovery Act; or

3. there has been or is likely to be an increase in imports of articles that are like or directly competitive with articles which are or were produced by such firm or subdivision.

Also, in order for an affirmative determination to be made for secondarily affected workers of a firm and a certification issued regarding eligibility to apply for worker adjustment assistance, each of the group eligibility requirements of Section 222(b) of the Act must be met.

(1) Significant number or proportion of the workers in the workers' firm or an appropriate subdivision of the firm have become totally or partially separated, or are threatened to become totally or partially separated;

(2) the workers' firm (or subdivision) is a supplier or downstream producer to a firm (or subdivision) that employed a group of workers who received a certification of eligibility to apply for trade adjustment assistance benefits and such supply or production is related to the article that was the basis for such certification; and

(3) either—

(A) The workers' firm is a supplier and the component parts it supplied for the firm (or subdivision) described in paragraph (2) accounted for at least 20 percent of the production or sales of the workers' firm; or

(B) a loss or business by the workers' firm with the firm (or subdivision) described in paragraph (2) contributed importantly to the workers' separation or threat of separation.

In order for the Division of Trade Adjustment Assistance to issue a certification of eligibility to apply for Alternative Trade Adjustment Assistance (ATAA) for older workers, the group eligibility requirements of Section 246(a)(3)(A)(ii) of the Trade Act must be met.

1. Whether a significant number of workers in the workers' firm are 50 years of age or older.

2. Whether the workers in the workers' firm possess skills that are not easily transferable.

3. The competitive conditions within the workers' industry (i.e., conditions within the industry are adverse).

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact

date for all workers of such determination.

None.

Affirmative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

The following certifications have been issued. The date following the company name and location of each determination references the impact date for all workers of such determination.

The following certifications have been issued. The requirements of Section 222(a)(2)(A) (increased imports) and Section 246(a)(3)(A)(ii) of the Trade Act have been met.

85,440, PCE Paragon Solutions, Research Triangle Park, North Carolina. July 21, 2013.

85,440A, PCE Paragon Solutions, Huntsville, North Carolina. July 21, 2013.

85,544, Reach Road Manufacturing Corp., Williamsport, Pennsylvania. September 17, 2013.

85,548, Trega Corporation, Hamburg, Pennsylvania. September 22, 2013.

85,582, Ethox Medical LLC, Buffalo, New York. October 8, 2013.

85,607, Air System Components, Inc., Ponca City, Oklahoma. October 20, 2013.

85,554, Rogersville Tube Plant, Rogersville, Alabama. September 24, 2013.

Negative Determinations for Alternative Trade Adjustment Assistance

In the following cases, it has been determined that the requirements of 246(a)(3)(A)(ii) have not been met for the reasons specified.

None.

Negative Determinations for Worker Adjustment Assistance and Alternative Trade Adjustment Assistance

In the following cases, the investigation revealed that the eligibility criteria for worker adjustment assistance have not been met for the reasons specified.

Because the workers of the firm are not eligible to apply for TAA, the workers cannot be certified eligible for ATAA.

The workers' firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

85,441, Keystone Calumet, Inc., Chicago Heights, Illinois.

85,559, Weatherford International LLC, Houston, Texas.

85,581, AT&T Mobility Services LLC, Morristown, New Jersey.

85,586, Delta Dental of Pennsylvania, Mechanicsburg, Pennsylvania.

Determinations Terminating Investigations of Petitions for Worker Adjustment Assistance

After notice of the petitions was published in the **Federal Register** and on the Department's Web site, as required by Section 221 of the Act (19 U.S.C. 2271), the Department initiated investigations of these petitions.

The following determinations terminating investigations were issued because the petitioning groups of workers are covered by active certifications. Consequently, further investigation in these cases would serve no purpose since the petitioning group of workers cannot be covered by more than one certification at a time.

85,565, Carl Zeiss Vision, Inc., Independence, Missouri.

I hereby certify that the aforementioned determinations were issued during the period of *October 27, 2014 through October 31, 2014.* These determinations are available on the Department's Web site *www.tradeact/taa/taa_search_form.cfm* under the searchable listing of determinations or by calling the Office of Trade Adjustment Assistance toll free at 888–365–6822.

Signed at Washington DC, this 6th day of November 2014.

Michael W. Jaffe,

Certifying Officer, Office of Trade Adjustment Assistance.

[FR Doc. 2014–27557 Filed 11–20–14; 8:45 am]

BILLING CODE 4510–FN–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 14–121]

Notice of Information Collection

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of information collection.

SUMMARY: The National Aeronautics and Space Administration, 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 (Pub. L. 104–13, 44 U.S.C. 3506(c)(2)(A)).

DATES: All comments should be submitted within 30 calendar days from the date of this publication.

ADDRESSES: Interested persons are invited to submit written comments regarding the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 7th Street NW., Washington DC, 20543. Attention: Desk Officer for NASA.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Frances Teel, NASA PRA Clearance Officer, NASA Headquarters, 300 E Street SW., Mail Code JF000, Washington, DC 20546, *Frances.C.Teel@nasa.gov.*

I. Abstract

NASA's founding legislation, the Space Act of 1958, as amended, directs the agency to expand human knowledge of Earth and space phenomena and to preserve the role of the United States as a leader in aeronautics, space science, and technology. The NASA Office of Education administers the agency's national education activities in support of the Space Act, including the performance measurement and evaluation of educational projects and programs. This generic clearance will allow the NASA Office of Education to test and pilot with subject matter experts, secondary students, higher education students, educators, and interested parties new and existing information collection forms and assessment instruments for the purposes of improvement and establishing validity and reliability characteristics of the forms and instruments. Forms and instruments to be tested include program application forms, customer satisfaction questionnaires, focus group protocols, and project activity survey instruments. Methodological testing will include focus group discussions, pilot surveys to test new individual question items as well as the complete form and instrument. In addition, test-retest and similar protocols will be used to determine reliability characteristics of the forms and instruments. Methodological testing will assure that forms and instruments accurately and consistently collect and measure what they are intended to measure and that data collection items are interpreted precisely and consistently, all towards the goal of accurate Agency reporting while improving the execution of NASA Education project activities.

This 30-day FRN reflects a reduction in the estimated number of respondents, as published in the 60-day FRN, Volume 78, Number 237, pages 74169–74170 on Tuesday, December 10, 2013. The targeted respondent pool will include educators, pre-college, undergraduate, graduate, and post-graduate students

only. As a result of this reduction, the estimated cost burden associated with the amount of time it will take for each respondent to read the instructions, gather the information, and submit also decreased.

II. Method of Collection

Electronic, paper, and focus group interviews.

III. Data

Title: Generic Clearance for the NASA Office of Education Performance Measurement and Evaluation (Testing).

OMB Number: 2700–XXXX.

Type of review: New Generic Clearance.

Affected Public: Individuals and Households.

Estimated Number of Respondents: 3,358.

Estimated Annual Responses: Variable.

Estimated Time per Response: Variable.

Estimated Total Annual Burden Hours: 2,312.

Estimated Total Annual Cost: $31,876.37.

IV. Request for Comments

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) 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 automated collection techniques or the use of other forms of information technology.

Frances Teel,

NASA PRA Clearance Officer.

[FR Doc. 2014–27513 Filed 11–20–14; 8:45 am]

BILLING CODE 7510–13–P

THE NATIONAL FOUNDATION FOR THE ARTS AND THE HUMANITIES

Notice of Proposed Information Collection Requests: Museums for All

AGENCY: Institute of Museum and Library Services, National Foundation for the Arts and the Humanities.

ACTION: Notice, request for comments, collection of information.

SUMMARY: The Institute of Museum and Library Services (IMLS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). This pre-clearance consultation program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. By this notice, IMLS is soliciting comments concerning an information collection from museums participating in the *Museums for All* program.

A copy of the proposed information collection request can be obtained by contacting the individual listed below in the **ADDRESSES** section of this notice.

DATES: Written comments must be submitted to the office listed in the addressee section below on or before January 16, 2015.

IMLS is particularly interested in comments that help the agency to:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques, or other forms of information technology, e.g., permitting electronic submissions of responses.

ADDRESSES: Send comments to: Christopher J. Reich, Senior Advisor, Institute of Museum and Library Services, 1800 M St. NW., 9th Floor, Washington, DC 20036. Mr. Reich can be reached by Telephone: 202–653–4685, Fax: 202–653–4608, or by email at *creich@imls.gov,* or by teletype (TTY/TDD) for persons with hearing difficulty at 202–653–4614.

SUPPLEMENTARY INFORMATION:

I. Background

The Institute of Museum and Library Services is the primary source of Federal support for the Nation's 123,000 libraries and 35,000 museums. The Institute's mission is to inspire libraries and museums to advance innovation, learning and civic engagement. The Institute works at the national level and in coordination with State and local organizations to sustain heritage, culture, and knowledge; enhance learning and innovation; and support professional development. IMLS is responsible for identifying national needs for and trends in museum, library, and information services; measuring and reporting on the impact and effectiveness of museum, library and information services throughout the United States, including programs conducted with funds made available by IMLS; identifying, and disseminating information on, the best practices of such programs; and developing plans to improve museum, library and information services of the United States and strengthen national, State, local, regional, and international communications and cooperative networks (20 U.S.C. Chapter 72, 20 U.S.C. 9108).

II. Current Actions

The purpose of this collection is to support a program to increase access to museums for underserved audiences through *Museums for All,* a voluntary program inviting museums to allow Electronic Benefit Transfer (EBT) card holders to receive reduced-price admission to their facilities. This information collection will obtain data from participating museums needed to administer the program, such as institution contact information and a staff person to administer the program. Because this is a new program, additional information will be collected to assess implementation of the program components, the efficacy of Agency supplied materials, and the impact of the program.

Agency: Institute of Museum and Library Services.

Title: Museums for All.

OMB Number: To Be Determined.

Frequency: 1.

Affected Public: The target population is museums that choose to participate in the *Museums for All* program.

Number of Respondents: 125 in first year.

Estimated Average Burden per Response: The burden per respondent is estimated to be an average of 60 minutes.

Estimated Total Annual Burden: 125 hours (that is 60 minutes per respondent times 125 respondents equal 7,500 minutes or 125 hours).

Total Annualized capital/startup costs: n/a.

Total Annual costs: To be determined.

Public Comments Invited: Comments submitted in response to this notice will be summarized and/or included in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Christopher J. Reich, Senior Advisor, Institute of Museum and Library Services, 1800 M St. NW., 9th Floor, Washington, DC 20036. Mr. Reich can be reached by Telephone: 202–653–4685, Fax: 202–653–4608, or by email at *creich@imls.gov,* or by teletype (TTY/TDD) for persons with hearing difficulty at 202–653–4614. Office hours are from 8:30 a.m. to 5 p.m., E.T., Monday through Friday, except Federal holidays.

Dated: November 17, 2014.

Kim Miller,

Management Analyst.

[FR Doc. 2014–27652 Filed 11–20–14; 8:45 am]

BILLING CODE 7036–01–P

POSTAL REGULATORY COMMISSION

[Docket No. R2015–3; Order No. 2251]

International Mail Contract

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning a Type 2 rate adjustment and the filing of a related negotiated service agreement with PostNL. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 2, 2014.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction

On November 14, 2014, the Postal Service filed a notice, pursuant to 39 CFR 3010.40 *et seq.,* announcing a Type 2 rate adjustment in conjunction with a new negotiated service agreement.[1] The Notice concerns the inbound portion of a bilateral agreement with Royal PostNL BV (PostNL) (Agreement), which the Postal Service seeks to include within the Inbound Market Dominant Multi-Service Agreements with Foreign Postal Operators 1 (Docket Nos. MC2010–35, R2010–5 and R2010–6) product. Notice at 1.

II. Contents of Filing

The Postal Service's filing consists of the Notice, two attachments, and redacted and unredacted versions of an Excel file with supporting financial workpapers. *Id.* at 2. Attachment 1 is an application for non-public treatment of material filed under seal with the Commission. *Id.* Attachment 2 is a redacted copy of the Agreement. *Id.* The Postal Service includes a redacted version of the financial workpapers with its filing as a separate public Excel file.

The Postal Service states that the intended effective date of the Agreement is January 1, 2015; asserts that it is providing more than the 45 days advance notice required under 39 CFR 3010.41; and identifies the parties to the Agreement as the United States Postal Service and PostNL, the postal operator for the Netherlands. *Id.* at 3–4.

Reporting requirements. Rule 3010.43 requires the Postal Service to submit a detailed data collection plan. In lieu of a special data collection for the Agreement, the Postal Service proposes to report information on the Agreement through the Annual Compliance Report. *Id* at 7. The Postal Service also invokes, with respect to service performance measurement reporting under rule 3055.3(a)(3), the standing exception in Order No. 996 for all agreements filed in the Inbound Market Dominant Multi-Service Agreements with Foreign Postal Operators 1 product grouping. *Id.*

Consistency with applicable statutory criteria. The Postal Service observes that Commission review of a negotiated service agreement addresses three statutory criteria, whether the agreement: (1) improves the Postal Service's net financial position or enhances the performance of operational functions; (2) will not cause unreasonable harm to the marketplace; and (3) will be available on public and reasonable terms to similarly-situated mailers. *Id.* at 7–8 (citing 39 U.S.C. 3622(c)(10)). The Postal Service asserts that it addresses the first two criteria in its Notice and that the third is inapplicable, as there are no entities similarly situated to PostNL in terms of their ability to tender broad-based Letter Post flows from the Netherlands. *Id.* at 8.

Functional equivalence. The Postal Service addresses reasons why it considers the Agreement functionally equivalent to the Koninklijke TNT PostBV and TNT Post Pakketservice Benelux BV (TNT Agreement) baseline agreement, notwithstanding acknowledgement and identification of similarities and differences.[2] The Postal Service asserts that it does not consider that the specified differences detract from the conclusion that the Agreement is functionally equivalent to the baseline TNT Agreement. *Id.* at 11.

III. Commission Action

The Commission, in conformance with rule 3010.44, establishes Docket No. R2015–3 to consider issues raised by the Notice. The Commission invites comments from interested persons on whether the Agreement is consistent with 39 U.S.C. 3622 and the requirements of 39 CFR part 3010. Comments are due no later than December 2, 2014. The public portions of this filing can be accessed via the Commission's Web site (*http://www.prc.gov*). Information on how to obtain access to non-public material appears in 39 CFR part 3007.

The Commission appoints James F. Callow to represent the interests of the general public (Public Representative) in this docket.

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. R2015–3 for consideration of matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, James F. Callow is appointed to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

3. Comments by interested persons in this proceeding are due no later than December 2, 2014.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

[1] United States Postal Service Notice of Type 2 Rate Adjustment, Notice Filing Functionally Equivalent Agreement and Application for Nonpublic Treatment, November 14, 2014 (Notice).

[2] *Id.* at 8–11. See also Docket Nos. MC2010–35, R2010–5, and R2010–6, Order No. 549, Order Adding Inbound Market Dominant Multi-Service Agreements with Foreign Postal Operators 1 to the Market Dominant Product List and Approving Included Agreements, September 30, 2010; Docket No. R2013–9, Order No. 2148, Order Granting, in Part, Motion for Partial Reconsideration of Order No. 1864 and Modifying, in Part, Order No. 1864, August 11, 2014.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2014–27562 Filed 11–20–14; 8:45 am]

BILLING CODE 7710–FW–P

RAILROAD RETIREMENT BOARD

Actuarial Advisory Committee With Respect to the Railroad Retirement Account

Notice of Public Meeting

Notice is hereby given in accordance with Public Law 92–463 that the Actuarial Advisory Committee will hold a meeting on December 17, 2014, at 10:30 a.m. at the office of the Chief Actuary of the U.S. Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois, on the conduct of the 26th Actuarial Valuation of the Railroad Retirement System. The agenda for this meeting will include a discussion of the assumptions to be used in the 26th Actuarial Valuation. A report containing recommended assumptions and the experience on which the recommendations are based will have been sent by the Chief Actuary to the Committee before the meeting.

The meeting will be open to the public. Persons wishing to submit written statements or make oral presentations should address their communications or notices to the Actuarial Advisory Committee, c/o Chief Actuary, U.S. Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092.

Martha P. Rico,

Secretary to the Board.

[FR Doc. 2014–27542 Filed 11–20–14; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94–409, that the Securities and Exchange Commission will hold a Closed Meeting on Wednesday, November 19, 2014 at 4:00 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (7), 9(B) and (10) and 17 CFR 200.402(a)(3), (5), (7), 9(ii) and (10), permit consideration of the scheduled matter at the Closed Meeting.

Commissioner Gallagher, as duty officer, voted to consider the items listed for the Closed Meeting in closed session, and determined that no earlier notice thereof was possible.

The subject matter of the Closed Meeting will be:

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact the Office of the Secretary at (202) 551–5400.

Dated: November 19, 2014.

Brent J. Fields,

Secretary.

[FR Doc. 2014–27800 Filed 11–19–14; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73613; File No. SR–NYSEArca–2014–127]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Use of Derivative Instruments by the First Trust Preferred Securities and Income ETF

November 17, 2014.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on November 5, 2014, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to reflect a change to the means of achieving the investment objective applicable to the First Trust Preferred Securities and Income ETF (the ''Fund'') relating to its use of derivative instruments. The Fund is currently listed and traded on the Exchange under NYSE Arca Equities Rule 8.600 (''Managed Fund Shares''). The text of the proposed rule change is available on the Exchange's Web site at *www.nyse.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 self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Commission has approved listing and trading on the Exchange of shares (''Shares'') of the Fund under NYSE Arca Equities Rule 8.600, which governs the listing and trading of Managed Fund Shares on the Exchange.[4] The Shares are offered by the First Trust Exchange-Traded Fund III (the ''Trust''), which was organized as a Massachusetts business trust and is registered with the Commission as an open-end management investment company.[5]

First Trust Advisors L.P. (''First Trust Advisors'') is the investment adviser

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Commission originally approved the listing and trading of the Shares on the Exchange on February 8, 2013. *See* Securities Exchange Act Release No. 68870 (February 8, 2013), 78 FR 11245 (February 15, 2013) (SR–NYSEArca–2012–139) (''Prior Order''). *See also* Securities Exchange Act Release No. 68458 (December 18, 2012), 77 FR 76148 (December 26, 2012) (SR–NYSEArca–2012–139) (''Prior Notice,'' and together with the Prior Order, the ''Prior Release'').

[5] The Trust is registered under the Investment Company Act of 1940 (''1940 Act''). On February 28, 2014, the Trust filed with the Commission an amendment to its registration statement on Form N–1A (File Nos. 333–176976 and 811–22245) under the Securities Act of 1933 (''Securities Act'') and under the 1940 Act relating to the Fund (''Registration Statement''). The descriptions of the Shares and the Fund contained herein are based, in part, on information in the Registration Statement. In addition, the Commission has issued an order granting certain exemptive relief to the Trust under the 1940 Act. *See* Investment Company Act Release No. 30029 (April 10, 2012) (File No. 812–13795) (the ''Exemptive Order'').

(''Adviser'') to the Fund. Stonebridge Advisors LLC serves as sub-adviser (''Sub-Adviser'') to the Fund.

In this proposed rule change, the Exchange proposes to change the description of the Fund's use of derivative instruments, as described below.[6]

On December 6, 2012, the staff of the Commission's Division of Investment Management (''Division'') issued a no-action letter (''No-Action Letter'') relating to the use of derivatives by actively-managed exchange-traded funds (''ETFs'').[7] The No-Action Letter noted that, in March of 2010, the Commission announced in a press release that the staff was conducting a review to evaluate the use of derivatives by mutual funds, ETFs, and other investment companies and that, pending completion of this review, the staff would defer consideration of exemptive requests under the 1940 Act relating to, among others, actively-managed ETFs that would make significant investments in derivatives.

The No-Action Letter stated that the Division staff will no longer defer consideration of exemptive requests under the 1940 Act relating to actively-managed ETFs that make use of derivatives provided that they include representations to address some of the concerns expressed in the Commission's March 2010 press release. These representations are: (i) That the ETF's board periodically will review and approve the ETF's use of derivatives and how the ETF's investment adviser assesses and manages risk with respect to the ETF's use of derivatives; and (ii) that the ETF's disclosure of its use of derivatives in its offering documents and periodic reports is consistent with relevant Commission and staff guidance (together, the ''No-Action Letter Representations''). The No-Action Letter stated that the Division would not recommend enforcement action to the Commission under sections 2(a)(32), 5(a)(1), 17(a), 22(d), and 22(e) of the 1940 Act, or rule 22c–1 under the 1940 Act if actively-managed ETFs operating in reliance on specified orders (which include the Trust's Exemptive Order [8]) invest in options contracts, futures contracts or swap agreements provided that they comply with the No-Action Letter Representations.[9]

The Prior Release included the following representation: ''Consistent with the Exemptive Order, the Fund will not invest in options contracts, futures contracts, or swap agreements'' (the ''Derivatives Representation''). In view of the No-Action Letter, the Exchange is proposing to delete the Derivatives Representation.

The Exchange now proposes that, to pursue its investment objective, the Fund be permitted to invest in exchange-traded and over-the-counter (''OTC'') interest rate swaps, exchange-listed options on U.S. Treasury futures contracts, exchange-listed U.S. Treasury futures contracts, exchange-listed options on Eurodollar futures contracts, exchange-listed Eurodollar futures contracts, exchange-traded and OTC non-U.S. currency swaps, exchange-listed currency options, forward currency contracts and non-deliverable forward currency contracts (collectively, ''Derivative Instruments'').[10] The use of Derivative Instruments may allow the Fund to seek to enhance return, to hedge some of the risks of its investments in securities, to substitute a position in an underlying asset, to reduce transaction costs, to maintain full market exposure (which means to adjust the characteristics of its investments to more closely approximate those of the markets in which it invests), to manage cash flows, to preserve capital or to manage its foreign currency exposures.[11]

Under normal market conditions, no more than 20% of the value of the Fund's net assets will be invested in Derivative Instruments.[12] In addition, at least 90% of the Fund's net assets that are invested in exchange-listed options on U.S. Treasury futures contracts, exchange-listed U.S. Treasury futures contracts, exchange-listed options on Eurodollar futures contracts, exchange-listed Eurodollar futures contracts, and exchange-listed currency options will be invested in such instruments whose principal market is a member of the Intermarket Surveillance Group (''ISG''), which includes all U.S. national securities exchanges, certain U.S. futures exchanges and certain foreign exchanges, or are parties to a comprehensive surveillance sharing agreement with the Exchange.[13]

The Prior Release stated that the Fund's investments would be consistent with the Fund's investment objective and would not be used to enhance leverage. In view of the Exchange's proposal to permit the Fund to use Derivative Instruments, the Fund's investments in Derivative Instruments could potentially be used to enhance leverage. However, the Fund's investments in Derivative Instruments will be consistent with the Fund's investment objective and will not be used to seek to achieve a multiple or inverse multiple of an index.

Investments in Derivative Instruments will be made in accordance with the 1940 Act and consistent with the Fund's investment objective and policies. The Fund will comply with the regulatory requirements of the Commission to maintain assets as ''cover,'' maintain segregated accounts, and/or make margin payments when it takes

[6] The Adviser represents that the Adviser and the Sub-Adviser have managed and will continue to manage the Fund in the manner described in the Prior Release and the Rule 144A Representation (as defined below), and will not implement the changes described herein until the instant proposed rule change is operative.

[7] *See* No-Action Letter dated December 6, 2012 from Elizabeth G. Osterman, Associate Director, Office of Exemptive Applications, Division of Investment Management.

[8] *See* note 5, *supra.*

[9] The Adviser acknowledges that, for the Fund to rely on the No-Action Letter, the Fund must comply with the No-Action Letter Representations, which include the following: (i) The Board of Trustees of the Trust (the ''Trust Board'') will periodically review and approve the Fund's use of derivatives and how the Adviser assesses and manages risk with respect to the Fund's use of derivatives and (ii) the Fund's disclosure of its use of derivatives in its offering documents and periodic reports will be consistent with relevant Commission and staff guidance.

[10] Non-deliverable forward currency contracts do not involve physical exchange of the two currencies of the subject contract, but instead a net cash settlement of the two currencies is made by one party to the other and is based upon the movement of the two currencies relative to each other. The net cash settlement occurs in a predetermined convertible currency. Non-deliverable forward currency contracts differ from conventional forward currency contracts in that there is not a physical exchange of the subject currencies at settlement, and non-deliverable forward currency contracts can be used on currencies that may be less liquid and/or have a smaller market of trade.

[11] In particular, the Sub-Adviser contemplates that the Fund will utilize Derivative Instruments for hedging purposes. For example, the Sub-Adviser may seek to use futures contracts or swap agreements to hedge the Fund's assets against higher rates by reducing its [sic] overall duration.

[12] The Fund will limit its direct investments in futures, options on futures and swaps to the extent necessary for the Adviser to claim the exclusion from regulation as a ''commodity pool operator'' with respect to the Fund under Rule 4.5 promulgated by the Commodity Futures Trading Commission (''CFTC''), as such rule may be amended from time to time. Under Rule 4.5 as currently in effect, the Fund will limit its trading activity in futures, options on futures and swaps (excluding activity for ''bona fide hedging purposes,'' as defined by the CFTC) such that it will meet one of the following tests: (i) Aggregate initial margin and premiums required to establish its futures, options on futures and swap positions will not exceed 5% of the liquidation value of the Fund's portfolio, after taking into account unrealized profits and losses on such positions; or (ii) aggregate net notional value of its futures, options on futures and swap positions will not exceed 100% of the liquidation value of the Fund's portfolio, after taking into account unrealized profits and losses on such positions.

[13] For a list of the current members of ISG, *see www.isgportal.org.* As stated in the Prior Release, the Exchange notes that not all components of the Disclosed Portfolio for the Fund may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

positions in Derivative Instruments involving obligations to third parties (*i.e.,* instruments other than purchase options). If the applicable guidelines prescribed under the 1940 Act so require, the Fund will earmark or set aside cash, U.S. government securities, high grade liquid debt securities and/or other liquid assets permitted by the Commission in a segregated custodial account in the amount prescribed.[14]

The Fund will include appropriate risk disclosure in its offering documents, including leveraging risk. Leveraging risk is the risk that certain transactions of the Fund, including the Fund's use of Derivative Instruments, may give rise to leverage, causing the Fund to be more volatile than if it had not been leveraged.[15]

Based on the above, the Exchange seeks this modification regarding the Fund's use of Derivative Instruments. The Adviser represents that there is no change to the Fund's investment objective. The Adviser and the Sub-Adviser believe that the ability to invest in Derivative Instruments will provide the Sub-Adviser with additional flexibility to meet the Fund's investment objective.

The Exchange further notes that the Prior Release stated that the Fund may hold up to an aggregate amount of 15% of its net assets in illiquid securities (calculated at the time of investment), including, among other enumerated assets, Rule 144A securities. To clarify this statement given that Rule 144A securities are not necessarily ''illiquid,'' the Adviser now represents that the Fund's limitation on holding up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment) would include Rule 144A securities deemed illiquid by the Adviser or Sub-Adviser, in accordance with Commission guidance (the ''Rule 144A Representation'').[16]

The Fund will continue to comply with all initial and continued listing requirements under NYSE Arca Equities Rule 8.600.

Except for the changes noted herein, all other facts presented and representations made in the Rule 19b–4 filing underlying the Prior Release remain unchanged.

The changes described herein will be effective upon (i) the effectiveness of an amendment to the Trust's Registration Statement disclosing the Fund's intended use of Derivative Instruments and (ii) when this proposed rule change has become operative. The Adviser represents that the Adviser, has managed and will continue to manage the Fund in the manner described in the Prior Release and the Rule 144A Representation, and will not implement the changes described herein until this proposed rule change is operative.

Impact on Arbitrage Mechanism

The Adviser believes there will be minimal, if any, impact to the arbitrage mechanism as a result of the use of derivatives. Market makers and participants should be able to value derivatives as long as the positions are disclosed with relevant information. The Adviser believes that the price at which Shares trade will continue to be disciplined by arbitrage opportunities created by the ability to purchase or redeem Creation Units (as defined below) at their net asset value (''NAV''), which should ensure that Shares will not trade at a material discount or premium in relation to their NAV.

The Adviser does not believe there will be any significant impacts to the settlement or operational aspects of the Fund's arbitrage mechanism due to the use of derivatives. Certain derivatives may not be eligible for in-kind transfer, and such derivatives will be substituted with a ''cash in lieu'' amount (as described below) when the Fund processes purchases or redemptions of Creation Units (as defined below) in-kind.

Creation and Redemption of Shares

The Fund will issue and redeem Shares on a continuous basis, at NAV, only in large specified blocks each consisting of 50,000 Shares (each such block of Shares, a ''Creation Unit''). The Fund will issue and redeem Creation Units in exchange for an in-kind portfolio of instruments and/or cash in lieu of such instruments (the ''Creation Basket''). In addition, if there is a difference between the NAV attributable to a Creation Unit and the market value of the Creation Basket exchanged for the Creation Unit, the party conveying instruments with the lower value will pay to the other an amount in cash equal to the difference (referred to as the ''Cash Component''). Cash will be conveyed in lieu of any Derivative Instruments that cannot be transferred in-kind.

The Fund's custodian, through the National Securities Clearing Corporation, will make available on each business day, prior to the opening of business of the New York Stock Exchange, the list of the names and quantities of the instruments comprising the Creation Basket, as well as the estimated Cash Component (if any), for that day. The published Creation Basket will apply until a new Creation Basket is announced on the following business day.

Valuation for Purposes of Calculating Net Asset Value

As indicated in the Prior Release, the Fund's NAV is determined as of the close of trading (normally 4:00 p.m., Eastern Time) on each day the New York Stock Exchange is open for business and is calculated by taking the market value of the Fund's total assets, including interest or dividends accrued but not yet collected, less all liabilities, and dividing such amount by the total amount of Shares outstanding.

For purposes of calculating NAV, the Fund's investments are valued daily at market value or, in the absence of market value with respect to any such investment, at fair value, in each case in accordance with valuation procedures (which may be revised from time to time) adopted by the Trust Board (the ''Valuation Procedures'') and in accordance with the 1940 Act. All valuations are subject to review by the Trust Board or its delegate. A market

[14] With respect to guidance under the 1940 Act, *see* 15 U.S.C. 80a–18; Investment Company Act Release No. 10666 (April 18, 1979), 44 FR 25128 (April 27, 1979); *Dreyfus Strategic Investing,* Commission No-Action Letter (June 22, 1987); *Merrill Lynch Asset Management, L.P.,* Commission No-Action Letter (July 2, 1996).

[15] To mitigate leveraging risk, the Fund will segregate or ''earmark'' liquid assets or otherwise cover the transactions that may give rise to such risk.

[16] A change regarding the restriction on the Fund's investments in Rule 144A securities was reflected in a supplement to the Registration Statement, dated March 31, 2014. The Commission has stated that long-standing Commission guidelines have required open-end funds to hold no more than 15% of their net assets in illiquid securities and other illiquid assets. *See* Investment Company Act Release No. 28193 (March 11, 2008), 73 FR 14618 (March 18, 2008), footnote 34. *See also,* Investment Company Act Release No. 5847 (October 21, 1969), 35 FR 19989 (December 31, 1970) (Statement Regarding ''Restricted Securities''); Investment Company Act Release No. 18612 (March 12, 1992), 57 FR 9828 (March 20, 1992) (Revisions of Guidelines to Form N–1A). A fund's portfolio security is illiquid if it cannot be disposed of in the ordinary course of business within seven days at approximately the value ascribed to it by the fund. *See* Investment Company Act Release No. 14983 (March 12, 1986), 51 FR 9773 (March 21, 1986) (adopting amendments to Rule 2a–7 under the 1940 Act); Investment Company Act Release No. 17452 (April 23, 1990), 55 FR 17933 (April 30, 1990) (adopting Rule 144A under the Securities Act).

The Commission previously has approved listing and trading on the Exchange of issues of Managed Fund Shares that may invest up to an aggregate amount of 15% of a fund's net assets in Rule 144A securities deemed illiquid by a fund's adviser, in accordance with Commission guidance. *See, e.g.,* Securities Exchange Act Release No. 71067 (December 12, 2013), 78 FR 76669 (December 18, 2013) (order approving listing and trading of shares of the SPDR MFS Systematic Core Equity ETF, SPDR MFS Systematic Growth Equity ETF, and SPDR MFS Systematic Value Equity ETF under NYSE Arca Equities Rule 8.600).

valuation generally means a valuation (i) obtained from an exchange, an independent pricing service (''Pricing Service''), or a major market maker (or dealer) or (ii) based on a price quotation or other equivalent indication of value supplied by an exchange, a Pricing Service, or a major market maker (or dealer). The information summarized below is based on the Valuation Procedures as currently in effect; however, as noted above, the Valuation Procedures are amended from time to time and, therefore, such information is subject to change.

Exchange-listed options on U.S. Treasury futures contracts, exchange-listed U.S. Treasury futures contracts, exchange-listed options on Eurodollar futures contracts, exchange-listed Eurodollar futures contracts, and exchange-listed currency options will typically be valued at the closing price in the market where such instruments are principally traded. OTC and exchange-traded swaps will typically be valued using a Pricing Service. Forward currency contracts and non-deliverable forward currency contracts will typically be valued at the current day's interpolated foreign exchange rate, as calculated using the current day's spot rate, and the thirty, sixty, ninety, and one-hundred-eighty day forward rates provided by a Pricing Service or by certain independent dealers in such contracts.

Certain Derivative Instruments may not be able to be priced by pre-established pricing methods. Such Derivative Instruments may be valued by the Trust Board or its delegate at fair value. The use of fair value pricing by the Fund is governed by the Valuation Procedures and conducted in accordance with the provisions of the 1940 Act. As a general principle, the current ''fair value'' of an asset would appear to be the amount which the owner might reasonably expect to receive for the asset upon its current sale. The use of fair value prices by the Fund generally results in prices used by the Fund that may differ from current market valuations or official closing prices on the applicable exchange. A variety of factors may be considered in determining the fair value of Derivative Instruments.

Because foreign exchanges may be open on different days than the days during which an investor may purchase or sell Shares, the value of the Fund's Derivative Instruments that are traded on foreign exchanges may change on days when investors are not able to purchase or sell Shares. Derivative Instruments that are denominated in foreign currencies will be translated into U.S. dollars at the exchange rate of such currencies against the U.S. dollar as provided by a Pricing Service. All Derivative Instruments that are denominated in foreign currencies will be converted into U.S. dollars at the exchange rates in effect at the time of valuation.

Availability of Information

As described in the Prior Release, on each business day, before commencement of trading in Shares in the Core Trading Session on the Exchange, the Fund discloses on its Web site the Disclosed Portfolio as defined in NYSE Arca Equities Rule 8.600(c)(2) that will form the basis for the Fund's calculation of NAV at the end of the business day. *See* ''Disclosed Portfolio'' below.

Pricing information for Derivative Instruments will be available from major broker-dealer firms, subscription services, and/or Pricing Services and, in addition, for exchange-traded Derivative Instruments, from the exchanges on which they are traded.

Disclosed Portfolio

The Fund's disclosure of derivative positions in the Disclosed Portfolio will include information that market participants can use to value these positions intraday. On a daily basis, the Fund will disclose on the Fund's Web site the following information regarding each portfolio holding, as applicable to the type of holding: Ticker symbol, CUSIP number or other identifier, if any; a description of the holding (including the type of holding, such as the type of swap); the identity of the security or other asset or instrument underlying the holding, if any; for options, the option strike price; quantity held (as measured by, for example, par value, notional value or number of shares, contracts or units); maturity date, if any; coupon rate, if any; effective date, if any; market value of the holding; and the percentage weighting of the holding in the Fund's portfolio.

Surveillance

The Exchange represents that trading in the Shares will be subject to the existing trading surveillances, administered by the Financial Industry Regulatory Authority (''FINRA'') on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.[17] The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

FINRA, on behalf of the Exchange, will communicate as needed regarding trading in the Shares, exchange-listed options on U.S. Treasury futures contracts, exchange-listed U.S. Treasury futures contracts, exchange-listed options on Eurodollar futures contracts, exchange-listed Eurodollar futures contracts, and exchange-listed currency options with other markets and other entities that are members of the ISG, and FINRA, on behalf of the Exchange, may obtain trading information regarding trading in the Shares, exchange-listed options on U.S. Treasury futures contracts, exchange-listed U.S. Treasury futures contracts, exchange-listed options on Eurodollar futures contracts, exchange-listed Eurodollar futures contracts, and exchange-listed currency options from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares, exchange-listed options on U.S. Treasury futures contracts, exchange-listed U.S. Treasury futures contracts, exchange-listed options on Eurodollar futures contracts, exchange-listed Eurodollar futures contracts, and exchange-listed currency options from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.[18]

At least 90% of the Fund's net assets that are invested in exchange-listed options on U.S. Treasury futures contracts, exchange-listed U.S. Treasury futures contracts, exchange-listed options on Eurodollar futures contracts, exchange-listed Eurodollar futures contracts, and exchange-listed currency options will be invested in such instruments whose principal market is a member of the ISG.

[17] FINRA surveils trading on the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

[18] For a list of the current members of ISG, *see www.isgportal.org.* The Exchange notes that not all components of the Disclosed Portfolio for the Fund may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5) [19] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will continue to be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Equities Rule 8.600. The Fund will continue to comply with all initial and continued listing requirements under NYSE Arca Equities Rule 8.600.

Under the proposed rule change, the Fund seeks to invest in Derivative Instruments, consistent with the No-Action Letter. Under normal market conditions, no more than 20% of the value of the Fund's net assets will be invested in Derivative Instruments. The Fund's investments in Derivative Instruments will be consistent with the Fund's investment objective and will not be used to seek to achieve a multiple or inverse multiple of an index. Investments in Derivative Instruments will be made in accordance with the 1940 Act and consistent with the Fund's investment objective and policies. The Fund will comply with the regulatory requirements of the Commission to maintain assets as ''cover,'' maintain segregated accounts, and/or make margin payments when it takes positions in Derivative Instruments involving obligations to third parties (*i.e.,* instruments other than purchase options). If the applicable guidelines prescribed under the 1940 Act so require, the Fund will earmark or set aside cash, U.S. government securities, high grade liquid debt securities and/or other liquid assets permitted by the Commission in a segregated custodial account in the amount prescribed. Moreover, the Fund will include appropriate risk disclosure in its offering documents, including leveraging risk.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Adviser represents that there is no change to the Fund's investment objective. With respect to the proposal to permit the Fund to invest in Derivative Instruments, the Adviser represents that use of Derivative Instruments may allow the Fund to seek to enhance return, to hedge some of the risks of its investments in securities, to substitute a position in an underlying asset, to reduce transaction costs, to maintain full market exposure, to manage cash flows, to preserve capital or to manage its foreign currency exposures. In addition, such proposed change will provide the Sub-Adviser with additional flexibility in meeting the Fund's investment objective. The Adviser has represented that it believes there will be minimal, if any, impact to the arbitrage mechanism as a result of the use of derivatives. In addition, the Commission has previously approved the use of derivatives similar to those proposed herein by issues of Managed Fund Shares traded on the Exchange.[20] Consistent with the Prior Release, NAV will continue to be calculated daily and the NAV and Disclosed Portfolio (as defined in NYSE Arca Equities Rule 8.600(c)(2)) will be made available to all market participants at the same time.

With respect to the proposal that at least 90% of the Fund's net assets that are invested in exchange-listed options on U.S. Treasury futures contracts, exchange-listed U.S. Treasury futures contracts, exchange-listed options on Eurodollar futures contracts, exchange-listed Eurodollar futures contracts, and exchange-listed currency options will be invested in such instruments whose principal market is a member of the ISG, the Exchange notes that the Commission has previously approved such limitations for other funds listed on the Exchange under NYSE Arca Equities Rule 8.600.[21] In addition, such a representation assures that most applicable exchange-traded assets of the Fund will be assets whose principal market is an ISG member or a market with which the Exchange has a comprehensive surveillance sharing agreement.

With respect to the Adviser now representing that the Fund's limitation on holding up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment) would include Rule 144A securities deemed illiquid by the Adviser or Sub-Adviser, in accordance with Commission guidance, the Exchange notes that the Commission previously has approved listing and trading on the Exchange of issues of Managed Fund Shares that may invest up to an aggregate amount of 15% of a fund's net assets in Rule 144A securities deemed illiquid by the Adviser or Sub-Adviser, in accordance with Commission guidance.[22]

In accordance with the Prior Release, the Fund will monitor its portfolio liquidity on an ongoing basis to determine whether, in light of current circumstances, an adequate level of liquidity is being maintained, and will consider taking appropriate steps in order to maintain adequate liquidity if, through a change in values, net assets, or other circumstances, more than 15% of the Fund's net assets are held in illiquid assets.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an actively-managed exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted, the additional flexibility to be afforded to the Sub-Adviser by permitting the Fund to invest in Derivative Instruments under the proposed rule change is intended to enhance the Sub-Adviser's ability to meet the Fund's investment objective. FINRA, on behalf of the Exchange, will communicate as needed regarding trading in the Shares, exchange-listed options on U.S. Treasury futures contracts, exchange-listed U.S. Treasury futures contracts, exchange-listed options on Eurodollar futures contracts, exchange-listed Eurodollar futures contracts, and exchange-listed currency options with other markets and other entities that are members of the ISG, and FINRA, on behalf of the Exchange, may

[19] 15 U.S.C. 78f(b)(5).

[20] *See, e.g.,* Securities Exchange Act Release Nos. 73081 (September 11, 2014), 79 FR 55859 (September 17, 2014) (SR–NYSEArca–2014–20) (order approving listing and trading on the Exchange of shares of the Reality Shares DIVS ETF under NYSE Arca Equities Rule 8.600); 72882 (August 20, 2014), 79 FR 50964 (August 26, 2014) (SR–NYSEArca–2014–58) (order approving listing and trading on the Exchange of shares of the PIMCO Short-Term Exchange-Traded Fund and the PIMCO Municipal Bond Exchange-Traded Fund under NYSE Arca Equities Rule 8.600).

[21] *See, e.g.,* Securities Exchange Act Release Nos. 7882 (August 20, 2014) (SR–NYSEArca–2014–58) (order approving listing and trading on the Exchange of shares of the PIMCO Short-Term Exchange-Traded Fund and the PIMCO Municipal Bond Exchange-Traded Fund under NYSE Arca Equities Rule 8.600); 72641 (July 18, 2014), 79 FR 43108 (July 24, 2014) (SR–NYSEArca–2014–64) (order approving listing and trading on the Exchange of the ARK Innovation ETF, ARK Genomic Revolution ETF, ARK Industrial Innovation ETF, and ARK Web x.0 ETF under NYSE Arca Equities Rule 8.600).

[22] *See* note 16, *supra.*

obtain trading information regarding trading in the Shares, exchange-listed options on U.S. Treasury futures contracts, exchange-listed U.S. Treasury futures contracts, exchange-listed options on Eurodollar futures contracts, exchange-listed Eurodollar futures contracts, and exchange-listed currency options from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares, exchange-listed options on U.S. Treasury futures contracts, exchange-listed U.S. Treasury futures contracts, exchange-listed options on Eurodollar futures contracts, exchange-listed Eurodollar futures contracts, and exchange-listed currency options from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. At least 90% of the Fund's net assets that are invested in exchange-listed options on U.S. Treasury futures contracts, exchange-listed U.S. Treasury futures contracts, exchange-listed options on Eurodollar futures contracts, exchange-listed Eurodollar futures contracts, and exchange-listed currency options will be invested in such instruments whose principal market is a member of the ISG. In addition, as indicated in the Prior Release, investors will have ready access to information regarding the Fund's holdings, the PIV (as defined in the Prior Release), the Disclosed Portfolio (as defined in the Prior Release and as further described herein), and quotation and last sale information for the Shares.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes the proposed rule change will permit the Sub-Adviser additional flexibility in achieving the Fund's investment objective, thereby offering investors additional investment options.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[23] and Rule 19b–4(f)(6)(iii) thereunder.[24]

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–NYSEArca–2014–127 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2014–127. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2014–127 and should be submitted on or before December 12, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[25]

Kevin M. O'Neill,

Deputy Secretary.

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[23] 15 U.S.C. 78s(b)(3)(A).

[24] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[25] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73615; File No. SR–CME–2014–49]

Self-Regulatory Organizations; Chicago Mercantile Exchange Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Regarding Decision Not To Clear Security-Based Swaps

November 17, 2014.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on November 17, 2014, Chicago Mercantile Exchange Inc. (''CME Inc.'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change described in Items I and II below, which Items have been prepared primarily by CME Inc. CME Inc. filed the proposal pursuant to Section 19(b)(3)(A) of the Act[3] and Rule 19b–4(f)(6)[4] thereunder, so that the proposal

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

was effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

CME Inc. is filing the proposed rule change that is limited to its business as a derivatives clearing organization. More specifically, the proposed rule change clarifies that CME Inc. has decided not to clear security-based swaps (''SBSs'').[5] As a result, CME Inc. is removing references in Chapter 8–H (Credit Default Swaps Clearing) to SBSs.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, CME Inc. included statements concerning the purpose 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. CME Inc. has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

CME Inc. is registered as a derivatives clearing organization with the Commodity Futures Trading Commission (''CFTC'') and currently offers clearing services for many different futures and swaps products. To date, CME Inc. has never performed the functions of a clearing agency with respect to SBSs. This proposed rule change is designed to make explicit that CME Inc. has decided not to clear SBSs.

As a result of the above decision, CME Inc. is proposing to amend Rule 8H01 to explicitly state that CME Inc. will not clear SBSs, with the exception of Restructuring European Single Name CDS Contracts created following the occurrence of a Restructuring Credit Event in respect of an iTraxx Component Transaction.[6] The clearing of Restructuring European Single Name CDS Contracts will be a necessary byproduct after such time that CME Inc. begins clearing iTraxx Europe index CDS. As currently contemplated, CME Inc. will not permit market participants to increase, close out (other than due to the occurrence of a credit event) or otherwise affect the size of a position in a Restructuring European Single Name CDS Contract.[7]

Additionally, to remove references to SBSs, CME Inc. will accordingly amend or delete Rules 8H04 (CDS Clearing Member Obligations and Qualifications), 8H820 (Performance Bond for Security-Based Swaps), 8H930.C (Acceptable Performance Bond Deposits for CDS Products), 8H931 (Rule Changes Relating to Security-Based Swaps), 8H932 (Records Relating to Disciplinary Proceedings and Security-Based Swaps), 8H933 (Notice Regarding Certain Disciplinary Matters Related to Security-Based Swaps), 8H934 (Reports to CDS Clearing Members), and 8H938 (Summary Suspensions Relating to Security-Based Swap Clearing Activities).

CME Inc. believes the proposed rule change is consistent with the requirements of the Exchange Act, including Section 17A of the Exchange Act,[8] in general, and furthers the objectives of Section 17A(b)(3)(F),[9] in particular, in that it is designed to remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions, and in general, to protect investors and the public interest. The proposed rule change will provide adequate notice to the public that CME Inc. will not clear SBSs. Additionally, by deciding not to clear SBSs, CME Inc. believes that it will avoid subjecting non-security products to potentially ''duplicative or inconsistent regulation'' and will ''eliminate any potential inefficiencies and undue delays that could result from the requirement that the Commission review changes to rules primarily affecting clearing operations with respect to products that are not securities . . .'' [10] As a result, CME Inc. believes that the proposed rule change is consistent with the Exchange Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

CME Inc. does not believe that the proposed rule change will have any impact, or impose any burden, on competition. The proposed rule change merely makes explicit the fact that CME Inc. has decided not to clear SBSs. Because CME Inc. never performed, and will not perform, the functions of a clearing agency with respect to SBS, the proposed rule change will not affect any actual clearing activities of CME Inc. and should not have any burden on competition. In fact, CME Inc. believes that the proposed rule change will have a positive effect on competition since the proposal will result in the avoidance of ''potential legal uncertainty and market disruption caused by delays that could result from the requirement that the Commission undertake a full review'' of CME Inc.'s non-security products.[11]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

CME Inc. has not solicited, and does not intend to solicit, comments regarding this proposed rule change. CME Inc. has not received any unsolicited written comments from interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

CME Inc. has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [12] and Rule 19b–4(f)(6) [13] thereunder.

Because the proposed rule change (i) does not significantly affect the protection of investors or the public interest, (ii) does not impose any significant burden on competition, and (iii) does not become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [14] and Rule 19b–4(f)(6) [15] thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [16] normally does not become operative prior to 30 days after

[5] CME Inc.'s decision not to clear SBS is subject to the limited exception of clearing Restructuring European Single Name CDS Contracts, as more fully detailed below. All references herein to CME Inc.'s decision not to clear SBS should be read/understood in this context.

[6] CME Inc. plans to launch clearing services for iTraxx Europe index CDS products and will file a separate proposed rule change with the Commission in connection with its iTraxx proposal.

[7] CME Inc. will provide further details surrounding the clearing of iTraxx Europe index CDS, and Restructuring European Single Name CDS Contracts specifically, in a separate iTraxx rule filing.

[8] 15 U.S.C. 78q–1.

[9] 15 U.S.C. 78q–1(b)(3)(F).

[10] *See* Securities Exchange Act Release No. 34–69284 (April 9, 2013), 78 FR 21046 (April 9, 2013).

[11] *See* Securities Exchange Act Release No. 34–64832 (July 7, 2011), 76 FR 41056 (July 13, 2011).

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 17 CFR 240.19b–4(f)(6).

[14] 15 U.S.C. 78s(b)(3)(A)(iii).

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6).

the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[17] CME Inc. has asked the Commission to waive the five-day pre-filing requirement and the 30-day operative delay so that the proposed rule change may become operative immediately upon filing.[18] The Commission believes that waiver of the 30-day operative delay is appropriate, as CME Inc. has, to date, never performed the functions of a clearing agency with respect to SBSs, and the rule text removed or altered as a result the proposed rule change removes any ambiguity concerning CME Inc.'s ability or desire to perform the functions of a clearing agency with respect to SBSs. Therefore, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest and designates the proposed rule change as operative upon filing.[19]

At any time within 60 days of the filing of the proposed change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*), or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–CME–2014–49 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–CME–2014–49. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of CME Inc. and on CME Inc.'s Web site at *http://www.cmegroup.com/market-regulation/rule-filings.html.*

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–CME–2014–49 and should be submitted on or before December 12, 2014.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Kevin M. O'Neill,

Deputy Secretary.

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[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to submit to the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. 17 CFR 240.19b–4(f)(6)(iii). The Commission has waived the five-day pre-filing period in this case.

[19] Solely for purposes of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–73614; File No. SR–ISE–2014–43]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Designation of Longer Period for Commission Action on Proposed Rule Change Amending Its Information Barrier Rules

November 17, 2014.

On September 15, 2014, International Securities Exchange, LLC (the ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change amending its information barrier rules. The proposed rule change was published for comment in the **Federal Register** on October 6, 2014.[3] The Commission received one comment letter [4] on the proposed rule change and one rebuttal letter from the Exchange.[5]

Section 19(b)(2) of the Act [6] 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 these proposed rule changes should be disapproved. The 45th day for this filing is November 20, 2014.

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 review the comment letter submitted in response to the Notice, to review the Exchange's response to such comment letter, and to consider and take action on the Exchange's proposed rule change.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 73261 (October 6, 2014), 79 FR 60226 (''Notice'').

[4] *See* Letter from John Kinahan, Chief Executive Officer, Group One Trading, L.P., dated October 27, 2014.

[5] *See* Letter from Michael J. Simon, Secretary and General Counsel, International Securities Exchange, LLC, dated November 14, 2014.

[6] 15 U.S.C. 78s(b)(2).

Accordingly, pursuant to Section 19(b)(2)(A)(ii)(I) of the Act[7] and for the reasons stated above, the Commission designates January 2, 2015, 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 No. SR–ISE–2014–43).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2014–27571 Filed 11–20–14; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Aviation Rulemaking Advisory Committee; Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Aviation Rulemaking Advisory Committee (ARAC) meeting.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of the ARAC.

DATES: The meeting will be held on December 18, 2014, starting at 1:00 p.m. Eastern Standard Time. Arrange oral presentations by December 11, 2014.

ADDRESSES: The meeting will take place at the Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591, 5th floor, 5A/B/C Conference Rooms.

FOR FURTHER INFORMATION CONTACT: Renee Pocius, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591, telephone (202) 267–5093; fax (202) 267–5075; email *Renee.Pocius@faa.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. 2), we are giving notice of a meeting of the ARAC taking place on December 18, 2014, at the Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

The Agenda includes:

1. Request for Clarification:

a. Avionics Systems Harmonization Working Group (TAE)—Phase 2 Low Airspeed Alerting.

2. Status Reports From Active Working Groups:

a. AC 120–17A Maintenance Control by Reliability Methods (ARAC).

b. Airman Certification Systems Working Group (ARAC).

c. Airworthiness Assurance Working Group (TAE).

d. Engine Harmonization Working Group (TAE).

i. Engine Bird Ingestion.

ii. Engine Endurance Testing Requirements—Revision of Section 33.87.

e. Flight Test Harmonization Working Group (TAE)—Phase 2 Tasking.

3. New Tasks:

a. Transport Airplane Damage-Tolerance and Fatigue Evaluation (TAE).

b. Transport Airplane Crashworthiness and Ditching Evaluation (TAE).

c. Materials Flammability Working Group (TAE).

d. Aircraft Systems Information Security Protection (ASISP) Working Group.

4. ARAC Bylaws:

5. Status Report From the FAA:

Attendance is open to the interested public but limited to the space available. Please confirm your attendance with the person listed in the **FOR FURTHER INFORMATION CONTACT** section no later than December 11, 2014. Please provide the following information: Full legal name, country of citizenship, and name of your industry association, or applicable affiliation. If you are attending as a public citizen, please indicate so.

For persons participating by telephone, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section by email or phone for the teleconference call-in number and passcode. Callers outside the Washington metropolitan area are responsible for paying long-distance charges.

The public must arrange by December 11, 2014 to present oral statements at the meeting. The public may present written statements to the Aviation Rulemaking Advisory Committee by providing 25 copies to the Designated Federal Officer, or by bringing the copies to the meeting.

If you are in need of assistance or require a reasonable accommodation for this meeting, please contact the person listed under the heading **FOR FURTHER INFORMATION CONTACT**. Sign and oral interpretation, as well as a listening device, can be made available if requested 10 calendar days before the meeting.

Issued in Washington, DC, on November 18, 2014.

Lirio Liu,

Designated Federal Officer, Aviation Rulemaking Advisory Committee.

[FR Doc. 2014–27602 Filed 11–20–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Twenty-Ninth Meeting: RTCA Special Committee 224, Airport Security Access Control Systems

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

ACTION: Meeting notice of RTCA Special Committee 224, Airport Security Access Control Systems.

SUMMARY: The FAA is issuing this notice to advise the public of the twenty-ninth meeting of the RTCA Special Committee 224, Airport Security Access Control Systems.

DATES: The meeting will be held on December 10th, 2014 from 10:00 a.m.–2:00 p.m.

ADDRESSES: The meeting will be held at RTCA, Inc., 1150 18th Street NW., Suite 910, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of Special Committee 224. The agenda will include the following:

December 10th, 2014

- Welcome/Introductions/Administrative Remarks
- Review/Approve Previous Meeting Summary
- Report from the TSA
- Report on Safe Skies Document Distribution
- Request to RTCA Program Management Committee for Consideration of Operational Guidance Section Status
- Individual Document Section Reports
- Action Items for Next Meeting
- Time and Place of Next Meeting
- Any Other Business
- Adjourn

Attendance is open to the interested public but limited to space availability.

[7] 15 U.S.C. 78s(b)(2)(A)(ii)(I).

[8] 17 CFR 200.30–3(a)(31).

With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on November 13, 2014.

Mohannad Dawoud,

Management Analyst, NextGen, Program Oversight and Administration, Federal Aviation Administration.

[FR Doc. 2014–27545 Filed 11–20–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2014–0037]

Agency Information Collection Activities: Request for Comments for New Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: The FHWA has forwarded the information collection request described in this notice to the Office of Management and Budget (OMB) for approval of a new information collection. We published a **Federal Register** Notice with a 60-day public comment period on this information collection on September 3, 2014. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by December 22, 2014.

ADDRESSES: You may send comments within 30 days to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention DOT Desk Officer. You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burden; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. All comments should include the Docket number FHWA–2014–0037.

FOR FURTHER INFORMATION CONTACT: Jim Sinnette, Office of Innovative Program Delivery, 202–366–1561, *james.sinnette@dot.gov,* Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590. Office hours are from 8 a.m. to 4:30 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: FHWA Major Project Financial Plans and Project Management Plans.

OMB Control #: 2125–XXXX.

Background: Major projects are defined in section 106(h) of title 23, United States Code (U.S.C.), as projects receiving Federal financial assistance with an estimated total cost of $500,000,000, or other projects as may be identified by the Secretary. Major projects are typically large, complex projects designed to address major highway needs and require the investment of significant financial resources. Project sponsors of major projects are required to submit a project management plan and an annual financial plan to FHWA.

The preparation of the project management plan, as required by 23 U.S.C. 106(h)(2), ensures that clearly defined roles, responsibilities, procedures and processes are in effect to provide timely information to the project decision makers to effectively manage the scope, costs, schedules, quality of, and the Federal requirements applicable to, the project. The project management plan serves as a guide for implementing the major project and documents assumptions and decisions regarding communication, management processes, execution and overall project control.

The preparation of the annual financial plan, as required by 23 U.S.C. 106(h)(3), ensures that the necessary financial resources are identified, available, and monitored throughout the life of the project. An annual financial plan is a comprehensive document that reflects the project's scope, schedule, cost estimate, and funding structure to provide reasonable assurance that there will be sufficient funding available to implement and complete the entire project, or a fundable phase of the project, as planned.

Section 106(i) of title 23 requires project sponsors of other projects with an estimated total cost of $100,000,000 or more that is not covered by subsection (h) to prepare annual financial plans that are to be made available to the Secretary for review upon the request of the Secretary.

Respondents: Approximately 200 project sponsors per year.

Estimated Average Burden per Response: Approximately 40 hours for the initial submittal of each plan and 20 hours for each update.

Estimated Total Annual Burden: Approximately 40 initial plans and 160 plan updates are submitted each year. For a total of approximately, 4,800 hours each year.

Electronic Access: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.* Follow the online instructions for accessing the dockets.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued on: November 17, 2014.

Michael Howell,

Information Collections Officer.

[FR Doc. 2014–27599 Filed 11–20–14; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION [4910–RY]

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed CSX Railway Tunnel Project in Washington, District of Columbia

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by FHWA and Other Federal Agencies.

SUMMARY: This notice announces actions taken by the FHWA that are final within the meaning of 23 U.S.C. 139(l)(1). The actions relate to a proposed CSX Transportation, Inc. (CSX) Virginia Avenue Tunnel Project in Washington, DC. Those actions grant approvals for the 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 April 20, 2015. 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: Mr. Michael Hicks, Environmental/Urban Engineer, 1990 K Street, Suite 510, Washington, DC 20006–1103, (202) 219–3513; email: *Michael.Hicks@dot.gov.* The FHWA District of Columbia Division normal business hours are 8 a.m. to 4:30 p.m. (Eastern Time). You may also contact Mr. Faisal Hameed,

Deputy Chief Engineer, Project Development & Environment, Infrastructure Project Management Administration (IPMA), District Department of Transportation, 55 M Street SE., Suite 500, Washington, DC 20003; telephone: 202–671–2326; email: *Faisal.Hameed@dc.gov.* The District Department of Transportation normal business hours are 8:15 a.m. to 4:45 p.m.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA has taken final action by issuing a Record of Decision concerning approvals for the Virginia Avenue Tunnel Reconstruction Project in the District of Columbia. CSX, the owner of the Virginia Avenue Tunnel, requested approval from FHWA to allow the short-term closure of I–695 ramps located at 6th and 8th Streets SE and occupancy of a portion of the 11th Street Bridge right-of-way located on Interstate 695 (I–695) to allow the reconstruction of the Virginia Avenue Tunnel. The tunnel is located in the Capitol Hill neighborhood of Washington, DC beneath eastbound Virginia Avenue SE from 2nd Street SE to 9th Street SE; Virginia Avenue Park between 9th and 11th Streets; and the 11th Street Bridge right-of-way. The tunnel is also aligned on the south side of I–695.

The approval actions by FHWA and the laws under which such actions were taken are described in the Draft Environmental Impact Statement approved on July 2, 2013, the Final Environmental Statement approved on June 5, 2014, and in the FHWA Record of Decision (ROD) issued on November 4, 2014, and in other documents in the FHWA administrative record. The actions were also based on the DEIS public hearing held on July 31, 2013; public meetings held on September 14, 2011, November 30, 2011, May 21, 2012, September 27, 2012, July 1, 2014 and July 31, 2014; and public and agency comments. The FEIS, ROD, and other documents in the FHWA administrative record file are available by contacting the FHWA, or DDOT, at the addresses provided above. The FEIS and ROD can also be viewed and downloaded from the project Web site at *www.virginiaavenuetunnel.com* or viewed at the following locations: Southeast Neighborhood Library, 403 7th Street SE., Washington, DC 20003; or the Southwest Neighborhood Library, 900 Wesley Place SW., Washington, DC 20024.

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].

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]; Landscaping and Scenic Enhancement (Wildflowers), 23 U.S.C. 319.

4. Wildlife: Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536], Marine Mammal Protection Act [16 U.S.C. 1361], Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)], 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.]; Archeological Resources Protection Act of 1977 [16 U.S.C. 470(aa)–11]; Archeological and Historic Preservation Act [16 U.S.C. 469–469(c)]; Native American Grave Protection and Repatriation Act (NAGPRA) [25 U.S.C. 3001–3013].

6. Social and Economic: Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; American Indian Religious Freedom Act [42 U.S.C. 1996]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

7. Wetlands and Water Resources: Clean Water Act, 33 U.S.C. 1251–1377 (Section 404, Section 401, Section 319); 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.

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.

(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: November 12, 2014.

Joseph C. Lawson,

Division Administrator, District of Columbia.

[FR Doc. 2014–27468 Filed 11–20–14; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2014–0104; Notice 1]

JLG Industries, Inc., Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petition.

SUMMARY: JLG Industries, Inc. (JLG) has determined that certain JLG Triple-L utility trailers do not fully comply with paragraph S4.3.5 of Federal Motor Vehicle Safety Standard (FMVSS) No. 110, *Tire Selection and Rims and Motor Home/Recreation Vehicle Trailer Load Carrying Capacity Information for Motor Vehicles with a GVWR of 4,536 kilograms (10,000 pounds) or Less.* JLG has filed an appropriate report dated July 16, 2014, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.*

DATES: The closing date for comments on the petition is December 22, 2014.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited at the beginning of this notice and submitted by any of the following methods:

- Mail: Send comments by mail addressed to: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- Hand Deliver: Deliver comments by hand to: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except Federal Holidays.
- Electronically: Submit comments electronically by: Logging onto the Federal Docket Management System

(FDMS) Web site at *http://www.regulations.gov/.* Follow the online instructions for submitting comments. Comments may also be faxed to (202) 493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that your comments were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Documents submitted to a docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the Internet at *http://www.regulations.gov* by following the online instructions for accessing the dockets. DOT's complete Privacy Act Statement is available for review in the **Federal Register** published on April 11, 2000, (65 FR 19477–78).

The petition, supporting materials, and all comments received before the close of business on the closing date indicated below will be filed and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the extent possible. When the petition is granted or denied, notice of the decision will be published in the **Federal Register** pursuant to the authority indicated below.

SUPPLEMENTARY INFORMATION:

I. JLG's Petition: Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), JLG submitted a petition for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

This notice of receipt of JLG's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

II. Trailers Involved: Affected are approximately 2,940 JLG Triple-L utility trailers with a GVWR of less than 10,000 lbs. that were manufactured between August 2005 and July 2014.

III. Noncompliance: JLG explains that the noncompliance is that the tire and loading information placard does not contain the words ''The weight of the cargo should never exceed XXX kilograms or XXX pounds'' as required by paragraph S4.3.5 of FMVSS No. 110.

IV. Rule Text: Paragraph S4.3.5 of FMVSS No. 110 requires in pertinent part:

> S6.5 Requirements for trailers. Each trailer, except for an incomplete vehicle, must show the information specified in S4.3 (c) through (g), and may show the information specified in S4.3 (h) and (i), on a placard permanently affixed proximate to the certification label specified in 49 CFR Part 567. Additionally, each trailer must on its placard contain a cargo capacity statement expressed as ''The weight of cargo should never exceed XXX kilograms or XXX pounds'' in the same location on the placard specified for the ''vehicle capacity weight'' statement required by the standard . . .

V. Summary of JLG's Analyses: JLG stated its belief that the subject noncompliance is inconsequential to motor vehicle safety for the following reasons:

(A) With regard to trailers JLG states that there is no need to account for passenger weight when considering cargo weight because there are no designated seating positions on the trailer and all of the weight capacity is designated towards cargo. JLG also believes that providing the maximum load capacity for the trailer therefore provides the same information as providing the maximum weight of the cargo.

(B) Although the Tire and Loading Information label on the subject trailers do not contain the statement set forth in S4.3.5, the same information is provided on a separate label in the vicinity of the Tire and Loading Information label. That label states that the ''Max Load Capacity xxxx lbs'' and further instructs the operator to ''center load on deck.'' It also draws attention to the maximum carrying load of the trailer and ensures that drivers loading the trailer are aware of the maximum load capacity the trailer can carry—the precise information the regulatory text intends to be conveyed.

JLG has additionally informed NHTSA that it has corrected the noncompliance so that all future production trailer Tire and Loading Information labels will comply with FMVSS No. 110.

In summation, JLG believes that the described noncompliance of the subject trailers is inconsequential to motor vehicle safety, and that its petition, to exempt JLG from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120 should be granted.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject trailers that JLG no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve tire distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant trailers under their control after JLG notified them that the subject noncompliance existed.

Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8.

Jeffrey M. Giuseppe,

Acting Director, Office of Vehicle Safety Compliance.

[FR Doc. 2014–27588 Filed 11–20–14; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2014–0109; Notice 1]

RECARO Child Safety, LLC, Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of Petition.

SUMMARY: RECARO Child Safety, LLC (RECARO) has determined that certain RECARO child restraints do not fully comply with paragraph S5.1.1(a) of Federal Motor Vehicle Safety Standard (FMVSS) No. 213, *Child Restraints.* RECARO has filed an appropriate report and was received by NHTSA on July 30, 2014, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.*

DATES: The closing date for comments on the petition is December 22, 2014.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited at the beginning of this notice and submitted by any of the following methods:

• Mail: Send comments by mail addressed to: U.S. Department of

Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

• Hand Deliver: Deliver comments by hand to: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except Federal Holidays.

• Electronically: Submit comments electronically by: Logging onto the Federal Docket Management System (FDMS) Web site at *http://www.regulations.gov/.* Follow the online instructions for submitting comments. Comments may also be faxed to (202) 493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that your comments were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Documents submitted to a docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the Internet at *http://www.regulations.gov* by following the online instructions for accessing the dockets. DOT's complete Privacy Act Statement is available for review in the **Federal Register** published on April 11, 2000, (65 FR 19477–78).

The petition, supporting materials, and all comments received before the close of business on the closing date indicated below will be filed and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the extent possible. When the petition is granted or denied, notice of the decision will be published in the **Federal Register** pursuant to the authority indicated below.

SUPPLEMENTARY INFORMATION:

I. RECARO's Petition: Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), RECARO submitted a petition for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

This notice of receipt of RECARO's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

II. Child Restraints Involved: Affected are approximately 78,339 RECARO ProRide child restraints manufactured between April 9, 2010 and July 8, 2014 and approximately 42,303 RECARO Performance RIDE child restraints manufactured between January 15, 2013 and July 8, 2014.

III. Noncompliance: RECARO explains that the noncompliance is that the subject child restraints do not comply with the system integrity requirements of FMVSS No. 213 paragraph S5.1.1(a) when subjected to the dynamic test requirements of FMVSS No. 213 S6.1. During NHTSA's compliance tests with the Hybrid II Six Year Old Dummy and the Hybrid III Weighted Six Year Old Dummy configured to the child restraints with the internal harness and the child restraints attached to the test bench with a lap belt and top tether, the tether belt separated at the attachment point to the child restraints. The top tether belt separation exhibited a complete separation of a load bearing structural element and therefore does not comply with the requirements set forth in FMVSS No. 213 S5.1.1(a).

IV. Rule Text: Paragraph S5.1.1(a) of FMVSS No. 213 requires in pertinent part:

S5.1.1 Child Restraint System Integrity. When tested in accordance with S6.1 each child restraint system shall meet the requirements of paragraphs (a) through (c) of this section.

(a) Exhibit no complete separation of any load bearing structural element and no partial separation exposing either surfaces with a radius of less than 1/4 inch or surfaces with protrusions greater than 3/8 inch above the immediate adjacent surrounding contactable surface of any structural element of the system.

V. Summary of RECARO's Analyses: RECARO stated its belief that the subject noncompliance is inconsequential to motor vehicle safety for the following reasons:

(A) FMVSS Safety: RECARO believes that NHTSA's test procedure is in direct violation of the instructions and warnings included with each ProRIDE and Performance RIDE child restraint and would constitute a misuse of the child restraint by the consumer, as seen on page 36 of the ProRIDE/Performance RIDE instruction manuals. RECARO designed and tested the ProRIDE/Performance RIDE child restraints to meet FMVSS No. 213 requirements when tested according to the instruction manuals, which was developed from decades of research and experience in the automotive industry. Installation in accordance with the ProRIDE/Performance RIDE instruction manuals decreases the likelihood of top tether anchor failure from the vehicle. RECARO has limited lower anchor and top tether use for the ProRIDE/Performance RIDE since the inception of the RIDE platform, and recently lowered the LATCH (lower anchors and top tether attachment) limit to 45 pounds from the previously stated 52 pounds to meet current FMVSS No. 213 requirements. RECARO also made mention that NHTSA noted in its 2012 FMVSS No. 213 Final Rule response, limitations were added to the lower anchors to ''prevent lower LATCH anchor loads from exceeding their required strength level specified in FMVSS No. 225.'' RECARO states that they used this same rationale when they developed the RIDE platform in 2010 and concluded that a load limit of 52 pounds would be the safest for consumers.

(B) Structural Integrity: RECARO stated that technology has shown repeatedly that collapse, breakage, and crumpling of material minimizes energy and increases the rate of survival for the occupant in the event of a collision. They also stated that vehicles are designed to reduce the rate of acceleration, and more importantly deceleration, of passengers by crushing and breaking to absorb the energy. Thus, RECARO believes that child restraint technology has fallen in-line with vehicle technology in recent years and that other child restraints have been designated ''compliant'' even though their convertible shell-to-base connection has been designed to crack and break during the peak loading in a crash, due to life-saving decreases in injury criterion values. RECARO further stated that the top tether webbing has been designed to rip and break apart under extreme loads to allow the deceleration time to increase for the occupant in the crash event. Recaro states that if the injury criterion meets industry standards, then controlled breakage has proven multiple times to be a positive outcome in the event of a vehicle crash, as seen in the RIDE platform.

(C) Publications: RECARO cites the ''2013 LATCH Manual'' published by Safe Ride News Publication which confirms that top tether anchors in vehicles are becoming limited more frequently in the weight to which they can be subjected. The manual states that 16 vehicle models limit the use of top tethers to 65 pounds minus the weight of the child restraint when using the vehicle belt, and 27 vehicle models use the same tether limit rationale when installed with lower anchors. Recaro indicates that this demonstrates that a majority of vehicles on the road instruct consumers to use top tether load limit restrictions that align with RECARO's top tether load limit of 65 pounds minus the 20 pound weight of the child restraint equaling a 45 pound load limit. When installing the child restraint with a top tether and vehicle belt, 26 vehicle models advise to follow the child restraint manufacturer's instructions and an additional 3 vehicle models limit the child's weight to 48 pounds or less.

RECARO states that none of the examples above disagree with RECARO's warnings and installation instructions and therefore reduce consumer confusion when installing their child restraint. RECARO also states that they

have always supported the alignment of child restraint anchorage requirements and vehicle anchorage requirements for LATCH, such as the 2012 Final Rule which amended the testing requirements for lower anchor use above the combined weight of the child and the child restraint. RECARO says they would support NHTSA's review of its current testing requirements for top tether use and the consideration of either implementing similar load limitations for the top tether or requirements for the automotive industry to increase the load to which the tether anchorage can bear.

RECARO referred to documents published in the public docket for the 2012 Final Rule amendment of FMVSS No. 213 to limit lower anchor loads, which by request of NHTSA was performed by ALPHA Technology Associates. In this document, which was used to justify the increased risk of ''lower LATCH loads . . . exceeding their required strength,'' there is a table depicting top tether anchor loads at the point in which certain makes and models saw a quasi-static failure. In another study, the Transportation Research Center conducted similar testing of vehicles and found failure of the top tether of two models at 606 and 1,281 pounds of force.

RECARO believes that these documents, which were prepared for NHTSA, give validation to the reasoning by RECARO to limit the use of the top tether.

(D) Previous NHTSA Decisions: RECARO is aware that NHTSA has a clear precedent of denying child restraint manufacturers' petitions for inconsequential noncompliance concerning top tether separation. However, RECARO believes that the environment in which those decisions were made has changed. Recaro claims that the methodology it uses to limit top tether loads actually increases safe installations of child restraints by limiting the pounds of force applied and decreasing the chance tether anchor load failures. RECARO also believes that in the event of tether separation the increase to risk of safety is non-existent because the head excursion limits were not exceeded in NHTSA's compliance tests. RECARO indicates that the risk of the subject child restraints impacting objects in the vehicle is identical to, or better than, other compliant child restraints because both restraints meet the same head excursion requirements.

Recaro noted that in an earlier denial of a petition for inconsequential noncompliance NHTSA noted that if it granted the petition it would be contradictory to NHTSA's mission to promote greater use of LATCH and tether. RECARO believes that this reasoning is no longer relevant due to the recently implemented limits on the use of lower anchors, and thus consumers are now more aware of the limits to the lower anchor and top tether which is consistent with guidance provided in RECARO's owner's manual.

(E) RECARO Accident Reports: Recaro states that its accident reports for the four years that the subject restraints have been on the market indicate no incidents of separation in the tether anchorage area. Recaro surmises the reason that tether separation occurs in testing is due to an outdated test bench seat and testing apparatus.

RECARO informed NHTSA that production and distribution of the subject child restraints affected by the noncompliance have been corrected effective July 9, 2014.

In summation, RECARO believes that the described noncompliance of the subject child restraints is inconsequential to motor vehicle safety, and that its petition, to exempt RECARO from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120 should be granted.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject child restraint that RECARO no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve child restraint distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant child restraint under their control after RECARO notified them that the subject noncompliance existed.

Authority: 49 U.S.C. 30118, 30120: Delegations of authority at 49 CFR 1.95 and 501.8.

Jeffrey M. Giuseppe,

Acting Director, Office of Vehicle Safety Compliance.

[FR Doc. 2014–27586 Filed 11–20–14; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2014–0113; Notice 1]

Harley-Davidson Motor Company, Inc., Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of Petition.

SUMMARY: Harley-Davidson Motor Company, Inc. (Harley-Davidson) has determined that certain MY 2015 Harley-Davidson model XG500 and model XG750 motorcycles do not fully comply with table 3, footnote 4, of Federal Motor Vehicle Safety Standard (FMVSS) No. 123, *Motorcycle Controls and Displays.* Harley-Davidson has filed an appropriate report dated September 3, 2014, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.*

DATES: The closing date for comments on the petition is December 22, 2014.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited at the beginning of this notice and submitted by any of the following methods:

- *Mail:* Send comments by mail addressed to: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Deliver:* Deliver comments by hand to: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except Federal Holidays.
- *Electronically:* Submit comments electronically by: logging onto the Federal Docket Management System (FDMS) Web site at *http://www.regulations.gov/.* Follow the online instructions for submitting comments. Comments may also be faxed to (202) 493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that your comments were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Documents submitted to a docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the Internet at *http://www.regulations.gov* by following the online instructions for accessing the dockets. DOT's complete Privacy Act Statement is available for review in the

Federal Register published on April 11, 2000, (65 FR 19477–78).

The petition, supporting materials, and all comments received before the close of business on the closing date indicated below will be filed and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the extent possible. When the petition is granted or denied, notice of the decision will be published in the **Federal Register** pursuant to the authority indicated below.

SUPPLEMENTARY INFORMATION:

I. Harley-Davidson's Petition: Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), Harley-Davidson submitted a petition for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

This notice of receipt of Harley-Davidson's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

II. Motorcycles Involved: Affected are approximately 3,929 MY 2015 Harley-Davidson model XG500 and model XG750 motorcycles manufactured from March 6, 2014 through August 12, 2014.

III. Noncompliance: Harley-Davidson explains that due to a label design error the numerals on the speedometers of the affected motorcycles are labeled at 20 mph intervals instead of 10 mph intervals as required by table 3, footnote 4, of FMVSS No. 123.

Rule Text: Footnote 4 of FMVSS No. 123 table 3 requires in pertinent part:

> . . . Major graduations and numerals appear at 10 mph intervals, minor graduations at 5 mph intervals. . .

V. Summary of HARLEY–DAVIDSON's Analyses: Harley-Davidson stated its belief that the subject noncompliance is inconsequential to motor vehicle safety for the following reasons:

(A) Harley-Davidson stated that FMVSS No. 123 does not require that motorcycles be equipped with speedometers. Specifically, the standard only requires that if motorcycles are in fact equipped with a speedometer, that the speedometer must be marked in 10 mph intervals. This has led Harley-Davidson to believe that NHTSA has implicitly acknowledged that a speedometer is not, itself, necessary for the safe operation of motorcycles, which is consistent with NHTSA's decision in 1982 to rescind FMVSS No. 122 which had required installation of speedometers on all vehicles.

(B) Harley-Davidson also stated that while the labeling error constitutes a technical noncompliance with table 3, footnote 4, of FMVSS No. 123, the noncompliance does not affect any aspect of vehicle performance—braking, steering, acceleration, visibility, etc. The speedometer remains fully visible to the operator and Harley-Davidson believes that the 20 mph numeral intervals adequately provide indication of speed to the rider.

(C) Harley-Davidson believes that the lack of 10 mph numerical labels will not present confusion for riders, as evidenced by the lack of complaints, claims or incidents. Furthermore, they believe that motorcycle owners typically also own and operate other vehicles, such as passenger cars and light trucks, which are not subject to any speedometer graduation requirements and which, in many cases, are equipped with speedometers with 20 mph numeral intervals.

Harley-Davidson has additionally informed NHTSA that beginning on August 22, 2014 it corrected the noncompliance so that all future production of the subject motorcycles comply with FMVSS No. 123.

In summation, Harley-Davidson believes that the described noncompliance of the subject motorcycles is inconsequential to motor vehicle safety, and that its petition, to exempt Harley-Davidson from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120 should be granted.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject motorcycles that Harley-Davidson no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant motorcycles under their control after Harley-Davidson notified them that the subject noncompliance existed.

Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8.

Jeffrey M. Giuseppe,

Acting Director, Office of Vehicle Safety Compliance.

[FR Doc. 2014–27587 Filed 11–20–14; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2014–0107; Notice 1]

Continental Tire the Americas, LLC, Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of Petition.

SUMMARY: Continental Tire the Americas, LLC (CTA) has determined that certain Continental General Altimax RT43 replacement tires do not fully comply with paragraphs S5.5(c) and (f) of Federal Motor Vehicle Safety Standard (FMVSS) No. 139, *New Pneumatic Radial Tires for Light Vehicles.* CTA has filed an appropriate report dated August 19, 2014, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.*

DATES: The closing date for comments on the petition is December 22, 2014.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited at the beginning of this notice and submitted by any of the following methods:

- Mail: Send comments by mail addressed to: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- Hand Deliver: Deliver comments by hand to: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except Federal Holidays.
- Electronically: Submit comments electronically by: logging onto the Federal Docket Management System (FDMS) Web site at *http://www.regulations.gov/.* Follow the online instructions for submitting comments. Comments may also be faxed to (202) 493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that your comments were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Documents submitted to a docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the Internet at *http://www.regulations.gov* by following the online instructions for accessing the dockets. DOT's complete Privacy Act Statement is available for review in the **Federal Register** published on April 11, 2000, (65 FR 19477–78).

The petition, supporting materials, and all comments received before the close of business on the closing date indicated below will be filed and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the extent possible. When the petition is granted or denied, notice of the decision will be published in the **Federal Register** pursuant to the authority indicated below.

SUPPLEMENTARY INFORMATION:

I. CTA's Petition: Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), CTA submitted a petition for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

This notice of receipt of CTA's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

II. Tires Involved: Affected are approximately 814 replacement tires that were manufactured for sale in the United States and Canada. CTA states that 181 of the replacement tires are still under their control. CTA further identified the tires as General Altimax RT43 brand 195/65R15 91T passenger car tires and General Altimax RT43 brand 195/65R15 91H passenger car tires.

III. Noncompliance: CTA explains that the noncompliance is that due to a mold labeling error the sidewall markings on both tires incorrectly describe the maximum inflation pressure as required by paragraph 5.5 (c) and the actual number plies in the tread area of the tires as required by paragraph S5.5(f) of FMVSS No. 139. Specifically, the 195/65R15 91T General Altimax RT43 tires were manufactured with ''Max Inflation Pressure: 350 kPa (51 PSI); Tread: 1 Polyester + 2 Steel + 2 Polyamide.'' The correct labeling and stamping should have been ''Max Inflation Pressure: 300 kPa (44 PSI); Tread: 1 Polyester + 2 Steel + 1 Polyamide.'' The 195/65R15 91H General Altimax RT43 tires were manufactured with ''Max Inflation Pressure 300 kPa (44 PSI); Tread: 1 Polyester + 2 Steel + 1 Polyamide.'' The correct labeling and stamping should have been ''Max Inflation Pressure 350 kPa (51 PSI); Tread: 1 Polyester + 2 Steel + 2 Polyamide.''

V. Rule Text: Paragraph S5.5(c) and (f) of FMVSS No. 139 requires in pertinent part:

> S5.5 Tire Markings. Except as specified in paragraphs (a) through (i) of S5.5, each tire must be marked on each sidewall with the information specified in S5.5(a) through (d) and on one sidewall with the information specified in S5.5(e) through (i) according to the phase-in schedule specified in S7 of this standard . . .
>
> (C) The maximum permissible inflation pressure, subject to the limitation of S5.5.4 through S5.5.6 of this standard;
>
> (f) The actual number of plies in the sidewall, and the actual number of plies in the tread area, if different;

V. Summary of CTA's Analyses: CTA stated its belief that the subject noncompliance is inconsequential to motor vehicle safety for the following reasons:

(A) Number of Plies: CTA believes that the mislabeling of the number of plies on the subject tires has no impact on the operational performance of the subject tires or on the safety of vehicles on which these tires are to be mounted. CTA states that the subject tires also meet or exceed all of the performance requirements specified by FMVSS No. 139.

(B) Max Inflation Pressure: CTA believes that the choice of the maximum inflation pressure level is the decision of the tire manufacturer, as long as it is in compliance with the established values under FMVSS No. 139 paragraph S5.5.4. CTA also believes that the maximum inflation pressure values of 350 kPa and 300 kPa on both tires are acceptable choices and stated that both tires can accommodate a maximum pressure of 350 kPa (51 PSI.)

(C) Overloading: CTA believes that the use of either of the maximum inflation pressures displayed on the subject tire sidewalls as the source of information for the recommended inflation pressure will not result in an overloading of the tires or their load carrying capacity. CTA says this is because both values (300 kPa and 350 kPa) are above the inflation pressure of 250 kPa (36 PSI) at which the tire's maximum load capacity is defined by the European Tyre and Rim Technical Organisation (ETRTO) standard.

(C) Strength: CTA stated that each standard load tire has a specified tire strength requirement. Which is defined in paragraph S6.5 of FMVSS No. 139 (and paragraph S5.3 of FMVSS No. 109) and must be met whether the selected maximum permissible pressure marking value is 240 kPa (35 PSI), 300 kPa (44 PSI), or 350 kPa (51 PSI). CTA believes that both of the subject tires meet this requirement.

(D) Incidents: CTA stated that they are not aware of any crashes, injuries, customer complaints, or field reports associated with the subject noncompliance.

(C) Previous Rulings: CTA made mention that NHTSA has previously granted tire companies inconsequentiality exemptions relating to errors in sidewall markings.

CTA has additionally informed NHTSA that it has corrected the noncompliance so that all future production of the subject tires comply with FMVSS No. 139.

In summation, CTA believes that the described noncompliance of the subject tires is inconsequential to motor vehicle safety, and that its petition, to exempt CTA from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120 should be granted.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject tires that CTA no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve equipment distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires under their control after CTA notified

them that the subject noncompliance existed.

Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8.

Jeffrey M. Giuseppe,

Acting Director, Office of Vehicle Safety Compliance.

[FR Doc. 2014–27585 Filed 11–20–14; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2014–0106; Notice 1]

Oreion Motors, LLC, Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petition.

SUMMARY: Oreion Motors, LLC (Oreion) has determined that certain 2011–2013 Oreion Reeper low speed vehicles, do not fully comply with paragraph S5.(b)(10) of Federal Motor Vehicle Safety Standard (FMVSS) No. 500 which requires installation of seat belts that conform to FMVSS No. 209, *Seat Belt Assemblies.* Oreion has filed an appropriate report dated August 13, 2014, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.*

DATES: The closing date for comments on the petition is December 22, 2014.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited at the beginning of this notice and submitted by any of the following methods:

- Mail: Send comments by mail addressed to: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- Hand Deliver: Deliver comments by hand to: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except Federal Holidays.
- Electronically: Submit comments electronically by: Logging onto the Federal Docket Management System (FDMS) Web site at *http://www.regulations.gov/.* Follow the online instructions for submitting comments. Comments may also be faxed to (202) 493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that your comments were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Documents submitted to a docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the Internet at *http://www.regulations.gov* by following the online instructions for accessing the dockets. DOT's complete Privacy Act Statement is available for review in the **Federal Register** published on April 11, 2000, (65 FR 19477–78).

The petition, supporting materials, and all comments received before the close of business on the closing date indicated below will be filed and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the extent possible. When the petition is granted or denied, notice of the decision will be published in the **Federal Register** pursuant to the authority indicated below.

SUPPLEMENTARY INFORMATION:

I. Oreion's Petition: Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), Oreion submitted a petition for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

This notice of receipt of Oreion's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

II. Low Speed Vehicles Involved: Affected are approximately 526 2011–2013 Oreion Reeper low speed vehicles originally manufactured with seatbelts manufactured by Changzhou Dongchen.

III. Noncompliance: Oreion explains that the noncompliance is that the seatbelts installed in the subject vehicles do not fully comply with the requirements of paragraph S5.(b)(10) of FMVSS No. 500 because the year that the seatbelts were manufactured is not included on the seatbelts as specified in paragraph S4.1(j) of FMVSS No. 209.

V. Rule Text: Paragraph S5.(b) of FMVSS No. 500 requires in pertinent part:

> (b) Each low-speed vehicle shall be equipped with: . . . (10) A Type 1 or Type 2 seat belt assembly conforming to Sec. 571.209 of this part, Federal Motor Vehicle Safety Standard No. 209, Seat belt assemblies, installed at each designated seating position.

Paragraph S4.1(j) of FMVSS No. 209 requires in pertinent part:

> S4.1(j) Marking. Each seat belt assembly shall be permanently and legibly marked or labeled with year of manufacture . . .

V. Summary of Oreion's Analyses: Oreion believes that the subject noncompliance is inconsequential to motor vehicle safety because they believe that the lack of the year of manufacture on the seat belts has no effect on the operational safety of the seat belts installed in the subject noncompliant vehicles.

Oreion stated its belief that the seat belts in the subject vehicles have functioned as deigned during normal use. They contend that this is supported by their observation that no vehicle owner has brought their vehicle back to a dealership for seat belt related repairs.

Oreion stated its awareness that the year date stamp may be used with the seat belt model number to identify seat belt assemblies recalled by the seat belt manufacturer. In the event of a safety related recall by the seat belt manufacturer, Oreion will cooperate with the seat belt manufacturer to identify the vehicle owners of the vehicles containing affected seat belts without the need for the year stamp on the label. Oreion believes that the model number and the build date of the vehicle will be sufficient to accomplish this task.

In summation, Oreion believes that the described noncompliance of the subject low speed vehicle's seat belt assemblies is inconsequential to motor vehicle safety, and that its petition, to exempt Oreion from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120, should be granted.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allows NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or

noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject low speed vehicles that Oreion no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant low speed vehicles under their control after Oreion notified them that the subject noncompliance existed.

Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8.

Jeffrey M. Giuseppe,

Acting Director, Office of Vehicle Safety Compliance.

[FR Doc. 2014–27582 Filed 11–20–14; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2013–0006; Notice 2]

General Motors, LLC, Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of Petition.

SUMMARY: General Motors, LLC (GM), has determined that certain model year (MY) 2007 through 2013 GM trucks and multipurpose passenger vehicles (MPVs) manufactured from June 19, 2006, through December 6, 2012 do not fully comply with paragraph S4.3 of Federal Motor Vehicle Safety Standard (FMVSS) No. 110, *Tire Selection and Rims for Motor Vehicles with a GVWR of 4,536 Kilograms or less.* GM filed an appropriate report dated December 19, 2012 pursuant to 49 CFR part 573 *Defect and Noncompliance Responsibility and Reports.*

ADDRESSES: For further information on this decision contact Stuart Seigel, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), telephone (202) 366–2587, facsimile (202) 366–5930.

SUPPLEMENTARY INFORMATION:

I. GM's Petition: Pursuant to 49 U.S.C. 30118(d) and 30120(h) and the rule implementing those provisions at 49 CFR Part 556, GM has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

Notice of receipt of the petition was published, with a 30-day public comment period, on June 27, 2013 in the **Federal Register** (78 FR 38801). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) Web site at: *http://www.regulations.gov/.* Then follow the online search instructions to locate docket number ''NHTSA–2013–0006.''

II. Vehicles Involved: Affected are approximately 5,690: MY 2007 through 2013 Chevrolet Silverado trucks, Suburban MPVs and Tahoe MPVs; MY 2007 through 2013 GMC Sierra trucks; MY 2012 GMC Yukon MPVs; and MY 2007, 2009, 2011, 2012 and 2013 Yukon XL MPV's. The affected vehicles were manufactured from June 19, 2006 through December 6, 2012.

III. Noncompliance: GM explains that the noncompliance is that the subject vehicles are equipped with special equipment options 9S1 & 9U3 and are built with 2 front seating positions separated by floor space. However, the tire and loading placards incorrectly indicate that the vehicles have 3 front seating positions and therefore do not fully comply with paragraph S4.3 of FMVSS No. 110.

IV. Rule Text: Paragraph S4.3 of FMVSS No. 110 requires in pertinent part:

> S4.3 Placard. Each vehicle, except for a trailer or incomplete vehicle, shall show the information specified in S4.3(a) through (g), and may show, at the manufacturer's option, the information specified in S4.3(h) and (i), on a placard permanently affixed to the driver's side B-pillar. In each vehicle without a driver's side B-pillar and with two doors on the driver's side of the vehicle opening in opposite directions, the placard shall be affixed on the forward edge of the rear side door. If the above locations do not permit the affixing of a placard that is legible, visible and prominent, the placard shall be permanently affixed to the rear edge of the driver's side door. If this location does not permit the affixing of a placard that is legible, visible and prominent, the placard shall be affixed to the inward facing surface of the vehicle next to the driver's seating position. This information shall be in the English language and conform in color and format, not including the border surrounding the entire placard, as shown in the example set forth in Figure 1 in this standard. At the manufacturer's option, the information specified in S4.3(c), (d), and, as appropriate, (h) and (i) may be shown, alternatively to being shown on the placard, on a tire inflation pressure label which must conform in color and format, not including the border surrounding the entire label, as shown in the example set forth in Figure 2 in this standard. The label shall be permanently affixed and proximate to the placard required by this paragraph. The information specified in S4.3(e) shall be shown on both the vehicle placard and on the tire inflation pressure label (if such a label is affixed to provide the information specified in S4.3(c), (d), and, as appropriate, (h) and (i)) may be shown in the format and color scheme set forth in Figures 1 and 2. If the vehicle is a motor home and is equipped with a propane supply, the weight of full propane tanks must be included in the vehicle's unloaded vehicle weight. If the vehicle is a motor home and is equipped with an on-board potable water supply, the weight of such on-board water must be treated as cargo . . .
>
> (b) Designated seated capacity (expressed in terms of total number of occupants and number of occupants for each front and rear seat location) . . .

V. Summary of GM'S Analyses: GM states that the error resulted in the following condition on the subject placards of these vehicles:

- The seating capacity for the front row seat is incorrectly shown as 3 instead of 2.
- The total seating capacity is overstated by 1. For example, the total seating capacity is incorrectly shown as 3 instead of 2 for the vehicles with one row of seats, and as 6 instead of 5 for the vehicles with two rows of seats.
- The vehicle capacity weight (expressed as a combined weight of occupants and cargo) on the placard is correct. The seating capacity error has no impact on the vehicle capacity weight.
- All other information (front, rear and spare tire size designations and their respective cold tire inflation pressures as well as vehicle capacity weight) on the subject placards is correct.

GM stated its belief that this noncompliance is inconsequential to motor vehicle safety for the following reasons:

1. The subject vehicles are equipped with two bucket seats with one seat belt each in the front row. GM believes that the number of seats and the number of seat belts installed in the vehicle will clearly indicate to the customers the actual seating capacity, and it will be apparent to any observer that there are only two front seating positions. Even if an occupant references the tire information placard to determine the vehicle's seating capacity, it will be readily apparent that the front row seating capacity is 2 and not 3.

2. The vehicle capacity weight (expressed as a combined weight of occupants and cargo) on the placard is correct. The seating capacity error has

no impact on the vehicle capacity weight, and therefore, there is no risk of vehicle overloading.

3. All information required for maintaining and/or replacing the front and rear tires is correct on the tire information placard of the subject vehicles.

4. All other applicable requirements of FMVSS No. 110 have been met.

5. GM is not aware of any customer complaints, incidents or injuries related to the incorrect seating capacity on the subject tire information placards.

GM additionally informed NHTSA that it has corrected the noncompliance so that all future production vehicles will fully comply with FMVSS No. 110.

In summation, GM believes that the described noncompliance of its vehicles is inconsequential to motor vehicle safety, and that its petition, to exempt from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120 should be granted.

VI. NHTSA Decision: NHTSA has reviewed and accepts GM's analyses that the subject noncompliance is inconsequential to motor vehicle safety. Specifically, while the tire and loading placards incorrectly indicate the number of seating positions, that labeling error alone poses little if any risk to motor vehicle safety since the number of seating positions is readily apparent in the subject vehicles. The widths and shapes of the seats, especially the bucket seats, along with the number of seat belt sets installed provides a sufficient indication as to the maximum number of occupants the subject vehicles are intended to carry.

In consideration of the foregoing, NHTSA has decided that GM has met its burden of persuasion that the FMVSS No. 110 noncompliance is inconsequential to motor vehicle safety. Accordingly, GM's petition is hereby granted and GM is exempted from the obligation of providing notification of, and a remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the 5,690 vehicles that GM no longer controlled at the time it determined that the noncompliance existed. However, the granting of this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires under their control after GM notified them that the subject noncompliance existed.

Authority: (49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8).

Jeffrey M. Giuseppe,

Acting Director, Office of Vehicle Safety Compliance.

[FR Doc. 2014–27584 Filed 11–20–14; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2014–0055; Notice 2]

Harley-Davidson Motor Company, Inc., Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition.

SUMMARY: Harley-Davidson Motor Company, Inc. (Harley-Davidson) has determined that certain model year (MY) 2009–2014 Harley-Davidson FL Touring motorcycles do not fully comply with paragraph S6.1.3 of Federal Motor Vehicle Safety Standard (FMVSS) No. 108, *Lamps, reflective devices, and associated equipment.* Harley-Davidson has filed an appropriate report dated April 7, 2014, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.*

ADDRESSES: For further information on this decision contact Mike Cole, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), telephone (202) 366–2334, facsimile (202) 366–5930.

SUPPLEMENTARY INFORMATION:

I. Harley-Davidson's Petition: Pursuant to 49 U.S.C. 30118(d) and 30120(h) (see implementing rule at 49 CFR part 556), Harley-Davidson submitted a petition for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

Notice of receipt of the petition was published, with a 30-day public comment period, on July 7, 2014 in the **Federal Register** (79 FR 38360). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) Web site at: *http://www.regulations.gov/.* Then follow the online search instructions to locate docket number ''NHTSA–2014–0055.''

II. Vehicles Involved: Affected are approximately 343,680 MY 2009–2014 Harley-Davidson FL Touring motorcycles manufactured between June 10, 2008 and March 25, 2014.

III. Noncompliance: Harley-Davidson explains that the noncompliance is that the location of the rear reflex reflectors on the subject vehicles are mounted between an average of 0.3″ to 0.7″ below the required 15″ height-above-road surface as required by paragraph S6.1.3 of FMVSS No. 108.

IV. Rule Text: Paragraph S6.1.3.1 of FMVSS No. 108 requires in pertinent part:

> S6.1.3.1 Each lamp, reflective device, and item of associated equipment must be securely mounted on a rigid part of the vehicle, other than glazing, that is not designed to be removed except for repair, within the mounting location and height limits as specified in Table I, and in a location where it complies with all applicable photometric requirements, effective projected luminous lens area requirements, and visibility requirements with all obstructions considered.

V. Summary of Harley-Davidson's Analyses: Harley-Davidson stated its belief that the subject noncompliance is inconsequential to motor vehicle safety for the following reasons:

- Harley-Davidson had a third-party conduct testing on the subject motorcycles and reflex reflectors and they exhibited no reduction in conspicuity as compared to compliant vehicles. The independent company tested five test heights, for a test range of 11″–15″ height above-road surface, and all five tests far exceeded the minimum required values at each of the 10 test points specified in Table XVI. Due to the substantial safety margin designed into these reflex reflectors, photometry remained well above the minimums even when mounted a full 4″ inches below the minimum mounting height.
- Harley-Davidson believes that the lower mounting height of these reflectors may actually increase conspicuity and motor vehicle safety compared to fully compliant (higher mounted) reflectors.
- Harley-Davidson notes that the United Nations ECE regulations specify a minimum mounting height of 9.84″ (240mm). And further notes that in one study of daytime side vehicle

conspicuity of motorcycles, NHTSA's researchers concluded that the mounting height of the side reflex reflectors (12 inches vs 15 inches) was an ''insignificant'' factor for vehicle identification distance.

• Harley-Davidson further states that under FMVSS No. 108, tail lamps and license plate lamps on motorcycles are required to be illuminated whenever the headlamp is activated. And that since all Harley-Davidson models are equipped with automatic headlights on (AHO) functionality, the headlamps and tail lamps are automatically illuminated when the ignition is in the on position, thus providing conspicuity during daylight and darkness while the motorcycle is operating.

Harley-Davidson also made reference to a withdrawal of rulemaking regarding a lower height for reflex reflectors.

Harley-Davidson has additionally informed NHTSA that it has corrected the noncompliance so that all future production motorcycles will comply with FMVSS No. 108.

In summation, Harley-Davidson believes that the described noncompliance of the subject vehicles is inconsequential to motor vehicle safety, and that its petition, to exempt Harley-Davidson from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120 should be granted.

NHTSA Decision

NHTSA Analysis: NHTSA has reviewed and accepts Harley-Davidson's analyses that the subject noncompliance is inconsequential to motor vehicle safety.

The primary function of a reflex reflector is to reduce accidents by permitting early detection of an unlighted motor vehicle approaching an intersection or parked by the side of the road. NHTSA has concluded that the test data provided by Harley-Davidson relative to the photometric performance of the reflex reflectors as mounted on the subject motorcycles is sufficient justification for NHTSA to concur with Harley-Davidson's assessment that the location of the rear reflex reflectors as mounted on the subject vehicles poses little if any risk to motor vehicle safety.

NHTSA Decision: In consideration of the foregoing, NHTSA has decided that Harley-Davidson has met its burden of persuasion that the FMVSS No. 108 noncompliance is inconsequential to motor vehicle safety. Accordingly, Harley-Davidson's petition is hereby granted and Harley-Davidson is exempted from the obligation of providing notification of, and a remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the subject motorcycles that Harley-Davidson no longer controlled at the time it determined that the noncompliance existed. However, the granting of this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant motorcycles under their control after Harley-Davidson notified them that the subject noncompliance existed.

Authority: (49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8).

Jeffrey M. Giuseppe,

Acting Director, Office of Vehicle Safety Compliance.

[FR Doc. 2014–27583 Filed 11–20–14; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Office of Hazardous Materials Safety; Notice of Application For Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of Applications for Special Permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR part 107, Subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein. Each mode of transportation for which a particular special permit is requested is indicated by a number in the ''Nature of Application'' portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before December 22, 2014.

ADDRESS COMMENTS TO: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Copies of the applications are available for inspection in the Records Center, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC or at *http://regulations.gov.*

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(1)); 49 CFR 1.53(b)).

Issued in Washington, DC, on November 13, 2014.

Donald Burger,

Chief, General Approvals and Permits.

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of special permits thereof
New Special Permits				
16267–N	.....	Korean Air Los Angeles, CA.	49 CFR 172.101 Column (9B), 172.204(c)(3), 173.27, and 175.30 (a)(1).	To authorize the one-time transportation in commerce of certain explosives that are forbidden for transportation by cargo only aircraft. (mode 4).

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of special permits thereof
16275–N		ThyssenKrupp Bilstein of America, Inc. Hamilton, OH.	49 CFR 173.306(f)(2)	To authorize the transportation in commerce of accumulators meeting the requirements of § 173.306(f)(2) except that the charge pressure may exceed 200 psig but may not exceed 320 psig. (modes 1,2).
16288–N		CE Kellogg Co. Inc. Vancouver, WA.	49 CFR 107.503(b), 107.503(c), 173.241, 173.242, 173.243.	To authorize the manufacture, mark, sale and use of a non-DOT specification glass fiber reinforced plastic (GFRP) cargo tank similar to a DOT Specification 407/412. (mode 1).
16291–N		Procter & Gamble Distributing LLC Cincinnati, OH.	49 CFR 172.301(c), 173.306 (a)(3)(ii).	To authorize the transportation in commerce of certain aerosol containers not fully conforming to specification DOT 2P. (mode 1).
16292–N		Standard Technologies, LLC Fremont, OH.	49 CFR 177.834(h), 178.700(c)(1).	To authorize the manufacture, mark, sale, and use of certain non-UN standard IBCs containing certain Class 3 liquids which may be discharged without removal from the motor vehicle. (mode 1).
16295–N		CYTEC INDUSTRIES INC. Woodland Park, NJ.	49 CFR 172.519(c)	To authorize the transportation in commerce of certain IBCs containing combustible liquids with a placard meeting the label specifications for size in § 172.407(c). (modes 1,3).
16302–N		Ametek Inc. Pittsburgh, PA.	49 CFR 171.1, 172.101 Columns (9A) and (9B), 173.303, 173.304.	To authorize the transportation in commerce of gases contained in glass ampules as not subject to the Hazardous Materials Regulations. (modes 1, 2, 3, 4, 5).
16304–N		GG Global Enterprizes LLC Phoenix, AZ.	49 CFR 173.196(a)	To authorize the manufacture, mark, sale, and use of alternative packaging for Ebola contaminated waste. (mode 1).
16307–N		Croman Corporation White City, OR.	49 CFR 172.101 Columns (8C) and (9B), 173.242, 175.310.	To authorize the transportation in commerce of certain flammable liquids in alternative packaging having a capacity of 119 gallons or more by cargo air. (mode 4).
16308–N		GeNO LLC Cocoa, FL	49 CFR 173.175	To authorize the transportation in commerce of permeation devices that are used in medical devices in lieu of use for calibrating air quality monitoring devices. (modes 1, 2, 3, 4, 5).

[FR Doc. 2014–27426 Filed 11–20–14; 8:45 am]
BILLING CODE 4909–60–M

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Actions on Special Permit Applications

AGENCY: Office of Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of actions on special permit applications.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR part 107, Subpart B), notice is hereby given of the actions on special permits applications in (October to October 2014). The mode of transportation involved are identified by a number in the ''Nature of Application'' portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft. Application numbers prefixed by the letters EE represent applications for Emergency Special Permits. It should be noted that some of the sections cited were those in effect at the time certain special permits were issued.

Issued in Washington, DC, on November 13, 2014.

Donald Burger,

Chief, Special Permits and Approvals Branch.

S.P. No.	Applicant	Regulation(s)	Nature of special permit thereof
Modification Special Permit Granted			
16266–M	Stericycle, Inc., Lake Forest	49 CFR 173.196(a)	To modify the special permit to authorize an additional packaging configuration.
11770–M	Gas Cylinder Technologies, Inc., Lakeshore, Ontario.	49 CFR 173.302a, and 173.304a.	To modify the special permit to authorize cargo and passenger aircraft as an additional mode of transportation.
New Special Permit Granted			
16144–N	Stage FX, Inc., Columbus, MT.	49 CFR 173.56(b) and 172.320.	To authorize the transportation in commerce of certain Class 1 materials without EX classification for approximately 15 miles by motor vehicle. (mode 1).
16174–N	Goal Zero, Bluffdale, UT	49 CFR 173.185(a)(1)	To authorize the transportation in commerce of certain lithium batteries that do not have the original UN test certifications by motor vehicle. (mode 1).

S.P. No.	Applicant	Regulation(s)	Nature of special permit thereof
		Emergency Special Permit Granted	
16263–N one-	Kalitta Air, LLC, Ypsilanti, MI	49 CFR 172.101 Column (9B), 172.204(c)(3), 173.27(b)(2) and (3) and 175.30(a)(1).	To authorize the time transportation in commerce of certain explosives that are forbidden for transportation by cargo only aircraft. (mode 4).
16266–N	Stericycle, Inc., Lake Forest, IL.	49 CFR 173.196(a)	To authorize the transportation in commerce of Ebola contaminated waste for disposal or incineration. (mode 1).
16279–N	Veolia ES Technical Solutions, L.L.C., Flanders, NJ.	49 CFR 173.196(a) and (b) ...	To authorize the transportation in commerce of ebola contaminated waste in alternative packaging. (mode 1).
16278–N	Stericycle, Inc., Lake Forest, IL.	49 CFR 173.196(a)	To authorize the transportation in commerce of Ebola contaminated medical waste in alternative packaging for disposal or incineration. (mode 1).
		New Special Permit Withdrawn	
16242–N	E.I. duPont de Nemours and Company, Wilmington, DE.	49 CFR 173.32(a)(2)	To authorize the transportation in commerce of two portable tanks that have been filled after the prescribed periodic inspection was due. (mode 1).
16296–N	Southern California Aviation, Victorville, CA.	49 CFR 173.56	To authorize the transportation in commerce of chemical oxygen generators. (modes 1, 4).
16126–N	Raytheon Missile Systems, Tucson, AZ.	49 CFR 173.62	To authorize the transportation in commerce of certain Cartridges, power device in UN5OB large packaging. (mode 1).
		Emergency Special Permit Withdrawn	
16282–N	Progressive Environmental Services, Inc., d-b-a, SWS Environmental Services, Panama City Beach, FL.	49 CFR 173.196(a)	To authorize the transportation in commerce of certain Ebola contaminated medical waste for autoclaving or incineration. (mode 1).

[FR Doc. 2014–27427 Filed 11–20–14; 8:45 am]
BILLING CODE 4910–60–M

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Delayed Applications

AGENCY: Office of Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of application delayed more than 180 days.

SUMMARY: In accordance with the requirements of 49 U.S.C. 5117(c), PHMSA is publishing the following list of special permit applications that have been in process for 180 days or more. The reason(s) for delay and the expected completion date for action on each application is provided in association with each identified application.

FOR FURTHER INFORMATION CONTACT: Ryan Paquet, Director, Office of Hazardous Materials Special Permits and Approvals, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

Key to "Reason for Delay"

1. Awaiting additional information from applicant.
2. Extensive public comment under review.
3. Application is technically complex and is of significant impact or precedent-setting and requires extensive analysis.
4. Staff review delayed by other priority issues or volume of special permit applications.

Meaning of Application Number Suffixes

N—New application
M—Modification request
R—Renewal Request
P—Party To Exemption Request

Issued in Washington, DC, on November 13, 2014.

Donald Burger,

Chief, General Approvals and Permits.

Application No.	Applicant	Reason for delay	Estimated date of completion
	Modification to Special Permits		
8451–M	Mustang Technology Group Plano, TX	4	11–30–2014
15642–M	Praxair Distribution, Inc. Danbury, CT	4	11–30–2014
9847–M	FIBA Technologies, Inc. (FIBA) Millbury, MA	4	11–30–2014
15832–M	Baker Petrolite Corporation (BPC) Sugar Land, TX	4	11–30–2014
14617–M	Western International Gas & Cylinders, Inc. Bellville, TX	4	11–30–2014
15866–M	Saft America Inc. Jacksonville, FL	4	11–30–2014
13359–M	BASF Corporation Florham Park, NJ	4	11–30–2014
	New Special Permit Applications		
15767–N	Union Pacific Railroad Company Omaha, NE	1	11–30–2014
15991–N	Dockweiler Neustadt-Glewe, Germany	4	11–30–2014

Application No.	Applicant	Reason for delay	Estimated date of completion
16001–N	VELTEK Malvern, PA	4	11–30–2014
16039–N	UTLX Manufacturing LLC Alexandria, LA	4	11–30–2014
16061–N	Battery Solutions, LLC Howell, MI	4	11–30–2014
16118–N	Toyota Motor Sales, U.S.A., Inc. Torrance, CA	4	11–30–2014
16121–N	U.S. Department of Defense (DOD) Scott AFB, IL	4	11–30–2014
16137–N	Diversified Laboratory Repair Gaithersburg, MD	4	11–30–2014
16142–N	Nantong CIMC Tank Equipment Co. Ltd. Jiangsu, Province	4	12–31–2014
16155–N	B.J. Alan Company dba Phantom Fireworks Canfield, OH	4	12–31–2014
16154–N	Patriot Fireworks, LLC Ann Arbor, MI	4	12–31–2014
Renewal Special Permits Applications			
11602–R	East Tennessee Iron & Metal, Inc. Rogersville, TN	4	11–30–2014
11860–R	GATX Corporation Chicago, IL	4	11–30–2014
15580–R	Wisconsin Central Ltd. Homewood, IL	4	11–30–2014

[FR Doc. 2014–27428 Filed 11–20–14; 8:45 am]

BILLING CODE 4910–60–M

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Notice of Application for Modification of Special Permit

AGENCY: Office of Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of Application for Modification of Special Permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR part 107, Subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the applications described herein. This notice is abbreviated to expedite docketing and public notice. Because the sections affected, modes of transportation, and the nature of application have been shown in earlier **Federal Register** publications, they are not repeated here. Requests for modification of special permits (e.g. to provide for additional hazardous materials, packaging design changes, additional mode of transportation, etc.) are described in footnotes to the application number. Application numbers with the suffix ''M'' denote a modification request. These applications have been separated from the new application for special permits to facilitate processing.

DATES: Comments must be received on or before December 8, 2014.

ADDRESS COMMENTS TO: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Copies of the applications are available for inspection in the Records Center, East Building, PHH–30, 1200 New Jersey Avenue Southeast, Washington, DC or at *http://regulations.gov.*

This notice of receipt of applications for modification of special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on November 13, 2014.

Donald Burger,

Chief, General Approvals and Permits.

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of special permits thereof
MODIFICATION SPECIAL PERMITS				
13220–M		Entegris Inc., Danbury, CT.	49 CFR 173.301; 173.302; 173.304; 173.315.	To modify the special permit to authorize additional hazardous materials.
14569–M		Northland Services Inc., Seattle, WA.	49 CFR 176.83	To modify the special permit to segregate Class I explosives from other hazardous materials when stowed on deck.
14778–M		Sea-Fire Marine Inc., Baltimore, MD.	49 CFR 173.301(f)	To modify the special permit to authorize cylinders being used on a foreign vessel to be transported for service while the vessel is in USA waters.
15491–M		Sea-Fire Marine Inc., Baltimore, MD.	49 CFR 173.301(f)	To modify the special permit to authorize cylinders being used on a foreign vessel to be transported for service while the vessel is in USA waters.

[FR Doc. 2014–27430 Filed 11–20–14; 8:45 am]

BILLING CODE 4910–60–M

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

November 17, 2014.

The Department of the Treasury will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before December 22, 2014 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimates, or any other aspect of the information collections, including suggestions for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.gov* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8141, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained by emailing *PRA@treasury.gov,* calling (202) 622–1295, or viewing the entire information collection request at *www.reginfo.gov.*

Internal Revenue Service (IRS)

OMB Number: 1545–1591.

Type of Review: Extension without change of a currently approved collection.

Title: TD 8994 (Reg-251701–96)—Electing Small Business Trusts.

Abstract: The final regulations relate to the qualification and treatment of electing small business trusts (ESBTs). The regulations interpret the rules added to the Internal Revenue Code (Code) by section 1302 of the Small Business Job Protection Act of 1996, section 1601 of the Taxpayer Relief Act of 1997, and section 316 of the Community Renewal Tax Relief Act of 2000. In addition, the final regulations provide that an ESBT, or a trust described in section 401(a) of the Code or section 501(c)(3) of the Code and exempt from taxation under section 501(a) of the Code, is not treated as a deferral entity for purposes of § 1.444–2T.

Affected Public: Businesses or other for-profits.

Estimated Annual Burden Hours: 7,500.

OMB Number: 1545–1649.

Type of Review: Extension without change of a currently approved collection.

Title: Revenue Procedure 99–21—Refunds and credits; period of limitations; financial disability.

Abstract: Revenue Procedure 99–21 describes the information that is required under § 6511(h)(2)(A) of the Internal Revenue Code in order to request suspension of the period of limitations under § 6511 for claiming a credit or refund of tax due to an individual taxpayer's financial disability. This information is required to be submitted with the taxpayer's claim for credit or refund of tax.

Affected Public: Individuals or households.

Estimated Annual Burden Hours: 24,100.

Brenda Simms,

Treasury PRA Clearance Officer.

[FR Doc. 2014–27569 Filed 11–20–14; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

United States Mint

Pricing for the 2014 Coin and Chronicles Set—Franklin D. Roosevelt

AGENCY: United States Mint, Department of the Treasury.

ACTION: Notice.

SUMMARY: The United States Mint is announcing a price of $57.95 for the 2014 Coin and Chronicles Set—Franklin D. Roosevelt.

FOR FURTHER INFORMATION CONTACT: Marc Landry, Acting Associate Director for Sales and Marketing; United States Mint; 801 Ninth Street NW., Washington, DC 20220; or call 202–354–7500.

Authority: 31 U.S.C. 5112.

Dated: November 14, 2014.

Richard A. Peterson,

Deputy Director, United States Mint.

[FR Doc. 2014–27650 Filed 11–20–14; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

Wait-Time Goals of the Department for the Veterans Choice Program

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In an interim final rule published by the Department of Veterans Affairs (VA) implementing the Veterans Choice Program (''the Program'') authorized by the Veterans Access, Choice, and Accountability Act of 2014, VA established start dates for participation in the Program for different groups of veterans depending upon their basis of eligibility to participate in the Program. In those regulations, VA stated that veterans who are eligible based upon being unable to schedule an appointment within the wait-time goals of the Veterans Health Administration, will be able to start receiving hospital care and medical services under the Program no later than December 5, 2014. VA also stated that if the start date for these veterans would be sooner than December 5, 2014, VA would publish a notice in the **Federal Register** advising the public of the faster implementation schedule. This Notice announces that November 17, 2014, is the start date for veterans eligible to participate in the Program.

FOR FURTHER INFORMATION CONTACT: Kristin Cunningham, Director, Business Policy, Chief Business Office (10NB), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 382–2508. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: In an interim final rule published by VA implementing the Veterans Choice Program (''the Program'') authorized by section 101 of the Veterans Access, Choice, and Accountability Act of 2014 (Pub. L. 113–146, ''the Act''), VA established start dates for participation in the Program for different groups of veterans depending upon their basis of eligibility to participate in the Program. In those regulations, at 38 CFR 17.1525(a)(2), VA stated that veterans who are eligible under § 17.1510(b)(1), based upon being unable to schedule an appointment within the wait-time goals of the Veterans Health Administration, will be able to start receiving hospital care and medical services under the Program no later than December 5, 2014. In § 17.1525(b), VA stated that if the start date for these veterans would be sooner than December 5, 2014, VA would publish a notice in the **Federal Register** advising the public of the faster implementation schedule. This Notice announces that November 17, 2014, is the start date for veterans eligible to participate in the Program under § 17.1510(b)(1).

VA was directed to establish the Program to furnish hospital care and

medical services through non-VA health care entities and providers to Veterans who either cannot be seen within the ''wait-time goals of the Veterans Health Administration'' or who qualify based on their place of residence. VA established this Program through an interim final rule published in the **Federal Register** on November 5, 2014. 79 FR 65571. This rulemaking created new regulations at 38 CFR 17.1500 through 17.1540 governing the Program. Section 17.1525 identified the start date for veterans to participate in the Program in relation to their basis of eligibility for the Program. Specifically, VA stated in section 17.1525(a)(1) that VA would begin furnishing hospital care and medical services under the Program to veterans whose eligibility was based on their place of residence, as defined in section 17.1510(b)(2) through (b)(4), on November 5, 2014. We also stated that VA would begin furnishing such care and services to veterans who are eligible for the Program under § 17.1510(b)(1) based on being unable to be seen within the wait-time goals of the Veterans Health Administration no later than December 5, 2014, under § 17.1525(a)(2). As explained in the supplementary information of the rulemaking, VA adopted this phased approach to implementation to ensure that we have the resources in place to support care for eligible veterans. We selected veterans eligible to participate based on their place of residence for the earlier start date because this population was more easily identified and less subject to change over time than those whose eligibility is based on being unable to be seen within the wait-time goals of the Veterans Health Administration.

Section 17.1525(b) specifies that if the start date would be earlier than December 5, 2014, for veterans whose eligibility is based on being unable to be seen within the wait-time goals of the Veterans Health Administration, then VA would notify the public by publishing a Notice of that start date in the **Federal Register**. VA has put in place the necessary resources to accommodate this population, and effective November 17, 2014, VA began making the Program available to these veterans.

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. Jose D. Riojas, Chief of Staff, Department of Veterans Affairs, approved this document on November 17, 2014, for publication.

Dated: November 18, 2014.

William F. Russo,

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

[FR Doc. 2014–27581 Filed 11–20–14; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

42 CFR Part 11
Clinical Trials Registration and Results Submission; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 11

[Docket Number NIH–2011–0003]

RIN 0925–AA52

Clinical Trials Registration and Results Submission

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: This Notice of Proposed Rulemaking proposes requirements for submitting registration and summary results information, including adverse event information, for specified clinical trials of drugs (including biological products) and devices and for pediatric postmarket surveillances of a device to ClinicalTrials.gov, the clinical trial registry and results data bank operated by the National Library of Medicine (NLM). This proposed rule provides for the expanded registry and results data bank specified in Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) to enhance patient enrollment, provide a mechanism to track subsequent progress of clinical trials, provide more complete results information, and enhance patient access to and understanding of the results of clinical trials. The proposed requirements would apply to the responsible party (meaning the sponsor or designated principal investigator) for certain clinical trials of drugs (including biological products) and devices that are regulated by the Food and Drug Administration (FDA) and for pediatric postmarket surveillances of a device that are ordered by FDA.

DATES: Comments are due on or before February 19, 2015.

ADDRESSES: Individuals and organizations interested in submitting comments, identified by RIN 0925–AA52 and Docket Number NIH–2011–0003, may do so by any of the following methods:

- *Electronic Submissions:* Use Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. To ensure timelier processing of comments, NIH is no longer accepting comments submitted directly to it by email. The NIH encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal: *http://www.regulations.gov.*
- *Written Submissions:* You may submit written submissions by Fax at 301–402–0169, or by Mail/Hand Delivery/Courier (For paper, disk, or CD–ROM submissions) to: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, MD 20852–7669.

Instructions: We welcome comments from the public on all issues set forth in this proposed rule, and on specific issues identified in the document. All submissions received must include the agency name, the Docket No., and Regulatory Information Number (RIN) for this rulemaking. All comments received at *http://www.regulations.gov* may be posted without change, including any personal information provided. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means NIH will not know your identity or contact information unless you provide it in the body of your comment.

You can assist us in considering your comment by referencing the number assigned to each key issue discussed in section III.C of this preamble or the number of the section of this proposed rule to which your comment relates.

For access to background documents or comments received, go to *http://www.regulations.gov* and insert the docket number found in the brackets in the heading of this document into the ''Search'' box and follow the prompts.

FOR FURTHER INFORMATION CONTACT: *Regulatory Process:* Jerry Moore, NIH Regulations Officer, Office of Management Assessment, telephone (301–496–4607) (not a toll-free number), Fax (301–402–0169), or by email at *jm40z@nih.gov*

Technical Information: Jerry Sheehan, Assistant Director for Policy Development, National Library of Medicine, National Institutes of Health, Department of Health and Human Services, telephone (301–496–6221) (not a toll-free number), Fax (301–402–2586), or by email at *sheehanjr@nlm.nih.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of This Regulatory Action

This proposed rule clarifies and expands requirements for the submission of clinical trial registration and results information to the ClinicalTrials.gov database, which is operated by the NLM. It implements the provisions of section 402(j) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)), which were added by FDAAA to improve public access to information about certain clinical trials of FDA-regulated drugs, biological products, and devices and certain pediatric postmarket surveillances of a device. Under section 402(j) of the PHS Act, those responsible for specified clinical trials of FDA-regulated products have been required to submit registration information to ClinicalTrials.gov since December 26, 2007, summary results information for clinical trials of approved products since September 27, 2008, and adverse events information since September 27, 2009. Section 402(j) of the PHS Act requires the Secretary of Health and Human Services (HHS) to use rulemaking to expand the requirements for submission of summary results information, and authorizes the Secretary to use rulemaking to make other changes in the requirements for submission of registration and results information.

This proposed rule does not impose requirements on the design or conduct of clinical trials or on the data that must be collected during clinical trials. Instead it specifies how data that were collected and analyzed in accordance with a clinical trial's protocol are to be submitted to ClinicalTrials.gov. No patient-specific data are required to be submitted by this proposed rule or by the law this proposed rule is intended to implement.

Summary of the Major Provisions of the Regulatory Action

Applicable Clinical Trial

This proposed rule specifies which clinical trials of FDA-regulated drugs, biological products, and devices and which pediatric postmarket surveillances of a device, are applicable clinical trials for which information must be submitted to ClinicalTrials.gov. This proposal specifies an approach for determining whether a particular clinical trial or study is an applicable clinical trial, based on descriptive information that would be submitted at the time of registration.

Responsible Party

This proposed rule specifies that there must be one (and only one) responsible party for submitting information about an applicable clinical trial. The sponsor of an applicable clinical trial would be considered the responsible party, unless and until the sponsor designates a qualified principal investigator as the responsible party. This proposed rule specifies the approach for determining who would be considered the sponsor of an applicable clinical trial under various conditions, what qualifies a principal investigator to be designated a responsible party by a sponsor, and how responsibility reverts to the sponsor if a designated principal investigator is unable to fulfill the requirement to

submit information to ClinicalTrials.gov.

Registration

This proposed rule specifies requirements for registering applicable clinical trials at ClinicalTrials.gov. It would require that the responsible party register an applicable clinical trial not later than 21 days after enrolling the first participant, and it specifies the data elements of clinical trial information that must be submitted at the time of registration. The proposed data elements include the descriptive information, recruitment information, location and contact information, and administrative data elements listed in section 402(j) of the PHS Act, as well as additional data elements that are proposed under the Secretary's authority to modify the requirements for clinical trial information due at registration as long as such modifications improve, and do not reduce, the clinical trial information available to the public in ClinicalTrials.gov. We consider the proposed additional data elements necessary to enable the Agency to implement other statutory provisions, indicate the status of human subjects protection review of the trial, facilitate the public's ability to search and retrieve information from ClinicalTrials.gov, and help ensure that entries are unambiguous. Some of these additional data elements were included in ClinicalTrials.gov before FDAAA was enacted.

Expanded Access Information

Section 402(j) of the PHS Act requires the submission of information on how to obtain expanded access to investigational drugs used in applicable clinical trials, if the drugs are available through expanded access programs to patients who are not participating in relevant clinical trials. For an applicable clinical trial of a drug that is available under expanded access, this proposed rule would require the submission of a separate expanded access record containing details about how to obtain access to the investigational drug. If an expanded access record has already been submitted in conjunction with a different clinical trial of that same drug, the responsible party for the new clinical trial could link to the existing expanded access record rather than create a new one.

Results Submission

This proposed rule implements the statutory requirement for the submission of summary results information for applicable clinical trials of drugs, biological products, and devices that are approved, licensed, or cleared by FDA. It also proposes to extend the requirement for results submission to applicable clinical trials of drugs, biological products, and devices that are not approved, licensed, or cleared by FDA. This proposed rule would require the submission of tables of data summarizing demographics and baseline characteristics of the enrolled participants and primary and secondary outcomes, including results of any scientifically appropriate statistical tests.

In general, this proposed rule would require the submission of results not later than 1 year after the completion date of the clinical trial, which is defined as the date of final data collection for the primary outcome measure studied. Results submission could be delayed for up to 2 additional years with certification that either an unapproved, unlicensed, or uncleared product studied in the trial is still under development by the manufacturer or that approval will be sought for a new use of an approved, licensed, or cleared product that is being studied in the trial. This proposed rule also permits responsible parties to request extensions to the results submission deadlines for ''good cause''.

Adverse Events

This proposed rule would require the responsible party to submit information summarizing the number and frequency of adverse events experienced by participants enrolled in a clinical trial, by arm and organ system. It would require submission of two tables of information: one summarizing all serious adverse events; and another summarizing other adverse events that occurred with a frequency of 5 percent or more in any arm of the clinical trial, regardless of whether such adverse events were anticipated or unanticipated.

Updates and Other Required Information

This proposed rule would require that all submitted information must be updated at least annually if there are changes to report. More rapid updating would be required for several data elements to help ensure that users of ClinicalTrials.gov have access to accurate, up-to-date information about important aspects of a clinical trial. This proposed rule also requires timely corrections to any errors discovered by the responsible party or the Agency during review of submissions.

Costs and Benefits

Based on our cost estimates, this regulatory action is not expected to have a significant impact on the economy. The costs consist primarily of the time needed to organize, format, and submit to ClinicalTrials.gov information that was prepared for or collected during the clinical trial (e.g., protocol information and clinical trial results). The benefits include greater public access to information about and evidence from applicable clinical trials (and other clinical trials) of FDA-regulated drugs, biological products, and devices, and greater clarity about what is required for those who are subject to the legal mandate to submit information to ClinicalTrials.gov.

Acronyms

AHRQ Agency for Healthcare Research and Quality
BLA Biologics License Application
CBER Center for Biologics Evaluation and Research, FDA
CDC Centers for Disease Control and Prevention
CDER Center for Drug Evaluation and Research, FDA
CDISC Clinical Data Interchange Standards Consortium
CDRH Center for Devices and Radiological Health, FDA
CFR Code of Federal Regulations
CONSORT Consolidated Standards of Reporting Trials
EMA European Medicines Agency
EU European Union
FAQ Frequently Asked Questions
FDA Food and Drug Administration
FDAAA Food and Drug Administration Amendments Act of 2007
FDAMA Food and Drug Administration Modernization Act of 1997
FD&C Act Federal Food, Drug, and Cosmetic Act
FOIA Freedom of Information Act
GCP Good Clinical Practices
HHS Department of Health and Human Services
ICH International Conference on Harmonisation of Technical Requirements of Pharmaceuticals for Human Use
ICMJE International Committee of Medical Journal Editors
ICTRP International Clinical Trials Registry Platform, WHO
IDE Investigational Device Exemption
IFPMA International Federation of Pharmaceutical Manufacturers and Associations
IND Investigational New Drug Application
IRB Institutional Review Board
IVD In Vitro Diagnostic
LPLV Last Patient Last Visit
MEDLINE® Medical Literature Analysis and Retrieval System Online
MedDRA Medical Dictionary for Regulatory Affairs
MeSH® Medical Subject Headings
MSSO Maintenance and Support Services Organization

NCT National Clinical Trial
NDA New Drug Application
NIH National Institutes of Health, HHS
NLM National Library of Medicine, NIH
NPRM Notice of Proposed Rulemaking
OHRP Office for Human Research Protections, HHS
OMB Office of Management and Budget
OTC Over-the-Counter
PDF Portable Document Format
PhRMA Pharmaceutical Research and Manufacturers of America
PHS Public Health Service
PI Principal Investigator
PRS Protocol Registration System
R&D Research and Development
RFA Request for Applications
RIA Regulatory Impact Analysis
RIN Regulatory Information Number
SAP Statistical Analysis Plan
SNOMED CT® Systematized Nomenclature of Medicine—Clinical Terms®
SPIRIT Standard Protocol Items for Randomized Trials
U.S.C. United States Code
WHO World Health Organization
XML Extensible Markup Language

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I. Overview of Statutory Provisions

This proposed rule would establish procedures and requirements for registering and submitting results information, including adverse event information, for certain clinical trials of drugs (including biological products) and devices and pediatric postmarket surveillances of a device necessary to implement section 402(j) of the PHS Act (42 U.S.C. 282(j)), as amended by Title VIII of FDAAA and including technical corrections made to FDAAA under Public Law 110–316 (referred to hereinafter as ''section 402(j) of the PHS Act'').

Title VIII of FDAAA, enacted on September 27, 2007, amends the PHS Act by directing the Secretary of HHS, acting through the Director of the National Institutes of Health (NIH or the Agency) to expand the existing clinical trial registry data bank known as ClinicalTrials.gov and to ensure that the data bank is publicly available through the Internet. Among other duties, NIH is directed to expand the data bank to include registration information for a broader set of clinical trials than were required to register under a previous law, the Food and Drug Administration Modernization Act of 1997 (FDAMA). Section 402(j) of the PHS Act specifies that identified entities or individuals, called responsible parties, are to submit registration information for certain applicable clinical trials of drugs (defined by section 402(j)(1)(A)(vii) of the PHS Act to include biological products) and devices, including any pediatric postmarket surveillance of a device required by FDA under section 522 of the FD&C Act. Section 402(j)(2)(A)(iii) of the PHS Act authorizes the Secretary of HHS to modify by regulation the data elements required for registration, provided that the Secretary provides a rationale for why such modification ''improves and does not reduce'' the information included in the data bank. The statute specifies certain deadlines by which registration information is to be submitted to the data bank.

Section 402(j)(3) of the PHS Act further directs the Agency to augment the registry data bank to include summary results information through a multistep process, as follows:

First, for those clinical trials that form the primary basis of an efficacy claim or are conducted after a product is approved, licensed, or cleared, the registry data bank is to be linked to selected existing results information available from the NIH and FDA (section 402(j)(3)(A) of the PHS Act). Such information includes citations to published journal articles focused on the results of applicable clinical trials, posted FDA summaries of FDA advisory committee meetings at which applicable clinical trials were considered, and posted FDA assessments of the results of any applicable drug clinical trials that were conducted under section 505A or 505B of the FD&C Act. Note that we use the term ''product'' hereinafter in this preamble to refer to either a drug (including a biological product), a device, or both, as each is defined in proposed § 11.10.

Second, for each applicable clinical trial subject to FDAAA, the responsible party must submit to the data bank results information required under section 402(j)(3)(C) of the PHS Act. Such information is to include tables of demographic and baseline characteristics of the ''patients who participated in the clinical trial'' (section 402(j)(3)(C)(i) of the PHS Act), i.e., the enrolled human subjects, and the primary and secondary outcome measures for each arm of the clinical trial, as well as a point of contact for scientific information about the clinical trial results and information on whether certain agreements exist between the sponsor and the principal investigator (PI) that limits the ability of the PI to discuss or publish the results of an applicable clinical trial after it is completed.

Third, section 402(j)(3)(D) of the PHS Act requires the Secretary to further expand the data bank by regulation ''to provide more complete results information and to enhance patient access to and understanding of the results of clinical trials.'' It requires consideration of specific issues in developing the regulations, in particular:

(1) Whether to require submission of results information for applicable clinical trials of products that are not approved, licensed, or cleared (whether approval, licensure, or clearance was sought) (See section 402(j)(3)(D)(ii)(II) of the PHS Act.); and if submission of clinical trial results information is required for such applicable clinical trials, the date by which that information is required to be submitted. (See section 402(j)(3)(D)(iv)(III) of the PHS Act.);

(2) Whether non-technical written summaries of the clinical trial and its results can be included in the data bank without being misleading or promotional. (See section 402(j)(3)(D)(iii)(I) of the PHS Act.);

(3) Whether technical written summaries of the clinical trial and its results can be included in the data bank without being misleading or promotional. (See section 402(j)(3)(D)(iii)(II) of the PHS Act.);

(4) Whether to require submission of the full clinical trial protocol or only such information on the protocol as may be necessary to help evaluate the results of the trial. (See section 402(j)(3)(D)(iii)(III) of the PHS Act.);

(5) Whether the 1-year period for submission of results information should be increased to a period not to exceed 18 months. (See section 402(j)(3)(D)(iv)(I) of the PHS Act.); and

(6) Whether requirements for results submission as proposed in this rule should apply to applicable clinical trials for which results information required under section 402(j)(3)(C) of the PHS Act is submitted before the effective date of the regulation imposing those requirements. (See section 402(j)(3)(D)(iv)(II) of the PHS Act.).

Section 402(j)(3)(D)(v) of the PHS Act further requires that the regulations shall establish:

(1) A standard format for the submission of clinical trial information. (See section 402(j)(3)(D)(v)(I) of the PHS Act.);

(2) Additional information on clinical trials and results written in nontechnical, understandable language for patients. (See section 402(j)(3)(D)(v)(II) of the PHS Act.);

(3) Procedures for quality control, with respect to completeness and content of clinical trial information, to help ensure that data elements are not false or misleading and are non-promotional. (See section 402(j)(3)(D)(v)(III) of the PHS Act.);

(4) Appropriate timing and requirements for updates of clinical trial information and whether and how such updates should be tracked. (See section 402(j)(3)(D)(v)(IV) of the PHS Act.);

(5) A statement to accompany the entry for an applicable clinical trial when primary and secondary outcome measures for such applicable clinical trial are submitted as a voluntary submissions after the date specified in section 402(j)(2)(C) of the PHS Act. (See section 402(j)(3)(D)(v)(V) of the PHS Act.); and

(6) Additions or modifications to the manner of reporting the data elements established under the results submission provisions of section 402(j)(3)(C) of the PHS Act. (See section 402(j)(3)(D)(v)(VI) of the PHS Act.).

Section 402(j)(3)(D)(vii) of the PHS Act requires the Secretary to convene a public meeting to solicit input from interested parties on those issues. The public meeting was convened on April 20, 2009, on the NIH campus. The public meeting attracted more than 200 registered participants and 60 written comments. All of the comments received prior to, during, and after the public meeting are available in the Clinical Trials Public Meeting Docket, ID: NIH–2009–0002, at Regulations.Gov: *http://www.regulations.gov/search/Regs/home.html#docketDetail?R=NIH-2009-0002.* We carefully reviewed the comments received in developing the proposed provisions that address the considerations enumerated in section 402(j)(3)(D) of the PHS Act. Many of the comments helped inform development of this proposed rule. For purposes of this rulemaking, we prepared a memorandum summarizing these comments and the issues commented upon [Ref. 1].

In addition, section 402(j)(3)(I)(i) of the PHS Act directs the Secretary to issue regulations to ''determine the best method for including in the registry and results data bank appropriate results information on serious adverse and frequent adverse events for applicable clinical trials (required to submit results under section 402(j)(3)(C) of the PHS Act) in a manner and form that is useful and not misleading to patients, physicians, and scientists.'' If regulations are not issued by September 27, 2009, then section 402(j)(3)(I)(ii) of the PHS Act specifies that the default provisions specified in section 402(j)(3)(I)(iii) of the PHS Act shall take effect, requiring the submission of certain information summarizing serious and frequent adverse events observed during an applicable clinical trial. Regulations were not issued by the deadline, so the default provisions required by sections 402(j)(3)(I)(ii) and (iii) of the PHS Act took effect on September 27, 2009. Section 402(j)(3)(I)(v) of the PHS Act indicates that adverse event information is ''deemed to be'' clinical trial information that is included in the data bank pursuant to the requirements for results submission under section 402(j)(3)(C) of the PHS Act.

Furthermore, section 402(j)(4)(A) of the PHS Act directs that the data bank accept ''voluntary submissions'' of complete registration or complete

results information for certain clinical trials for which such information would not otherwise required to be submitted, provided that the responsible party complies with requirements that could involve submission of information on additional clinical trials.

Section 801(c) of FDAAA requires the Secretary to issue guidance on how the requirements of section 402(j) of the PHS Act apply to a pediatric postmarket surveillance of a device, where that pediatric postmarket surveillance is not a clinical trial. This preamble and proposed rule address this topic and serve as the required guidance.

Section 402(j)(5) of the PHS Act specifies certain procedures and penalties related to non-compliance. Among other things, it directs NIH to post public notices of noncompliance in the data bank; requires report forms under certain HHS grants to include a certification that required registration and results submission under section 402(j) of the PHS Act are complete; prohibits HHS from funding responsible parties who do not fulfill their obligations under section 402(j) of the PHS Act; and grants FDA the authority to sanction responsible parties who fail to comply with section 402(j) of the PHS Act. Section 801(b) of FDAAA includes conforming amendments to the FD&C Act, which make failure to comply with specified requirements of section 402(j) of the PHS Act a prohibited act under the FD&C Act (See 21 U.S.C. 331(jj)(1)–(3).) Committing any such prohibited act could subject the violator to criminal and/or civil penalties, including civil money penalties.

Section 801(d) of FDAAA includes a preemption provision, which states that ''[u]pon the expansion of the registry and results data bank under section 402(j)(3)(D) of the Public Health Service Act, as added by this section, no State or political subdivision of a State may establish or continue in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database.''

II. Background

There is ongoing public interest in the transparency of information concerning clinical trials. The collection and public availability of information about clinical trials and their results is seen by many as an important public health issue. Advocates have argued that a central resource of clinical trial information is a potentially valuable tool to track the existence and progress of clinical trials and communicate their results, both positive and negative, as well as to provide potential participants with broad access to information about clinical trials seeking participants.

A. Clinical Trials Registration Prior to Passage of FDAAA

Registration of a limited set of clinical trials has been required by U.S. law since the U.S. Congress mandated the establishment of a clinical trial registry in 1997. Section 113 of FDAMA amended the PHS Act to require HHS, acting through NIH and in coordination with FDA and the Centers for Disease Control and Prevention (CDC), to establish, maintain, and operate a data bank of information on clinical trials testing the effectiveness of drugs for serious or life-threatening diseases and conditions, whether federally or privately funded, that are conducted under an Investigational New Drug application (IND). The statute required the data bank to include a description of the purpose of each drug, participant eligibility criteria, the location of the clinical trial sites, and a point of contact for those seeking to enroll in the clinical trial. The FDAMA requirements, which were modified slightly in 2002 by the Best Pharmaceuticals for Children Act (Pub. L. 107–109, 115 STAT 1408, 1420–21), are currently codified at 42 U.S.C. 282(i).

NLM, a part of NIH, developed the registry, known as ClinicalTrials.gov, in response to this mandate and in support of NLM's statutory mission to improve access to information to facilitate biomedical research and the public health. (See 42 U.S.C. 286(a).) The registry became publicly available in February 2000. ClinicalTrials.gov is an Internet-based data bank that informs the public about the conditions and interventions being investigated in clinical trials, eligibility criteria, the location of trial sites, and contact information. It also provides links to additional public information about disorders and interventions relevant to the research described.

While FDAMA required the registration of only certain clinical trials conducted under an IND, ClinicalTrials.gov accepts submissions of information about a broader range of clinical studies, in keeping with the long-standing authorities and responsibilities of HHS, the NIH, and the NLM. The PHS Act expressly directs the Secretary of HHS to ''collect and make available through publications and other appropriate means, information as to, and the practical application of,'' research concerning the treatment ''of physical and mental diseases and impairments of man.'' (See 42 U.S.C. 241(a).) The NLM is expressly required to support ''the dissemination and exchange of scientific and other information important to the progress of medicine and to the public health'' (See 42 U.S.C. 286(a).) Consequently, since its creation, ClinicalTrials.gov has accepted registration information on different types of clinical trials, including trials of drugs for other than serious or life-threatening diseases or conditions, trials of medical devices, surgical procedures, and behavioral interventions, and has also accepted registration of information on other types of clinical studies, such as observational studies. Prior to passage of FDAAA, ClinicalTrials.gov contained information on more than 45,000 clinical studies.

The clinical trial data elements and descriptions used in ClinicalTrials.gov prior to FDAAA [Ref. 2] were developed following public notice and comment on two guidance documents: (1) A final guidance issued by FDA in 2002 describing the information to be submitted to the ClinicalTrials.gov registry pursuant to the registration requirement set forth in section 113 of FDAMA [Ref. 3] (See 67 FR 12022, Mar.18, 2002.); and (2) a draft guidance issued by FDA in January 2004 [Ref. 4] (See 69 FR 3923, Jan. 27, 2004.), proposing revisions to the final guidance issued in 2002 to include information on additional submissions required pursuant to the Best Pharmaceuticals for Children Act (Pub. L. 107–109, 115 STAT 1408, 1420–21). This draft guidance was not finalized.

Following establishment of ClinicalTrials.gov, the scientific community, general public, industry, and others engaged in high-profile, public discussions about the need for increased access to information about clinical trials [Ref. 5]. For example, studies revealed that selective publication of clinical trial results could give a misleading picture about serious adverse effects of widely marketed drugs and about increased risks of such effects in certain segments of the population [Ref. 6].

The scientific and lay communities called for a range of new measures to improve access to and transparency of information about clinical trials, including broader mandatory registration and results submission. Incomplete access to information about clinical trials was seen by some to adversely affect investigators, journal editors, research funders, clinicians and participants. Proponents of more comprehensive registration of clinical trials in a publicly available data bank came from many quarters [Ref. 7, 8, 9]. For example, in 2004, the International Committee of Medical Journal Editors

(ICMJE) adopted a comprehensive trial registration policy aimed at increasing public access to trial information and preventing the selective publication of certain results. The updated 2007 ICMJE policy requires, as a condition for publication, registration of ''any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'' prior to the enrollment of the first participant [Ref. 10]. Industry groups also adopted registration policies. For example, in 2005, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) stated that ''all clinical trials [sponsored by member companies], other than exploratory trials, should be submitted for listing in a free, publicly accessible clinical trial registry within 21 days of the initiation of patient enrollment . . .''[Ref. 11]. In a follow-up statement, IFPMA allowed for the delayed release of information in any of five fields that ''may be regarded as sensitive for competitive reasons by the sponsor'' [Ref. 12]. Also in 2005, the World Health Organization (WHO) International Clinical Trial Registry Platform (ICTRP) Secretariat defined a 20-item minimum clinical trial registration dataset [Ref. 13]. The WHO minimum trial registration standard has been adopted broadly, including by the ICMJE, and does not allow withholding of the five fields considered ''sensitive'' by IFPMA. The European Union has passed legislation requiring the public disclosure of registration and results information for certain clinical trials of drugs that are conducted in European Union countries, including trials of drugs for pediatric indications. The European Medicines Agency (EMA) is engaged in a public consultation to develop detailed technical specifications for the information to be submitted [Ref. 14, 15].

Because ClinicalTrials.gov is compatible with and receptive to a variety of registration requirements, it may facilitate compliance with many laws and policies and attracts an extremely large and diverse group of data providers. Many trials are registered in ClinicalTrials.gov to satisfy the ICMJE policy, and the number of trials registered in ClinicalTrials.gov increased significantly after the announcement of the ICMJE policy [Ref. 16]. Clinical trial records in ClinicalTrials.gov account for more than 85 percent of trials in the registries searched by the WHO ICTRP Portal [Ref. 17]. We believe that the more comprehensive the data bank, the better suited it will be to serve public health goals, including those articulated in section 402(j) of the PHS Act. As a result, we continue to encourage sponsors and other entities associated with studies not subject to section 402(j) of the PHS Act to voluntarily register and submit the results of trials of all types of interventions and other types of clinical studies in ClinicalTrials.gov, bearing in mind that section 402(j)(4)(A) of PHS Act may apply to such submissions.

B. Implementation of Statutory Provisions Prior to Rulemaking

Due to the short statutory timelines for responsible parties to begin submitting registration and results information for applicable clinical trials under Title VIII of FDAAA, NIH proceeded to expand the ClinicalTrials.gov registry data bank immediately after enactment of FDAAA. The intent was to develop a data bank that would permit responsible parties to meet the statutory requirements to submit clinical trial information, even though regulations to clarify and expand those obligations had yet to be developed. In December 2007, NIH launched an expanded registry that could accommodate the submission of clinical trial registration information specified in section 402(j) of the PHS Act. It included all the registration data elements explicitly enumerated in section 402(j)(2)(A)(ii) of the PHS Act, as well as additional data elements that the Agency interpreted as necessary to meet other statutory requirements, maintain consistency with ClinicalTrials.gov data elements that were in place prior to FDAAA, and allow efficient operation of the data bank. Over time, the Agency posted information on the ClinicalTrials.gov Web site outlining its current thinking about the meaning of key terms defined in the statute, including ''applicable clinical trial'' and ''responsible party'' [Ref. 18].

In further expanding the data bank to accommodate the submission of results information specified in section 402(j)(3)(C) of the PHS Act, we commissioned a review of practices and standards used in existing results data banks [Ref. 19]; engaged in active dialogue with the clinical trial community, public and private sectors, including the patient community; and consulted with the NLM Board of Regents, which established a Working Group on Clinical Trials [Ref. 20] in late 2007 and held meetings open to the public in 2008 [Ref. 21] and 2009 [Ref. 22] that were announced in the **Federal Register** (73 FR 3473, Jan. 18, 2008; 74 FR 3627, Jan 21, 2009). We held discussions with other standards development bodies that are active in areas related to trial information, such as the Clinical Data Interchange Standards Consortium (CDISC) and Health Level Seven (HL7). We also reviewed and considered various approaches to preparing summary reports on the results of clinical trials, including the ICH–E3 Clinical Study Report format [Ref. 23], which is used to guide the submission of drug trial results to regulatory agencies in the U.S., Europe, and Japan, and the CONSORT statements [Ref. 24], which are used to guide the publication of trial results in the peer-reviewed literature. We found that the ICH–E3 format and CONSORT were designed to delineate the topics that should be included when preparing summary reports of trial results for their intended expert audiences (regulatory professionals and medical professionals, respectively). Both the ICH–E3 format and CONSORT recommend review and inclusion of information beyond that collected during an individual clinical trial. Neither addresses the communication of trial results to the general public, which is one of the intended audiences for data submitted to comply with section 402(j) of the PHS Act. We found no existing standards directly addressing the submission of summary results tables as required by Title VIII of FDAAA.

As a result of these consultations and the review of existing approaches to results reporting, we decided to develop a results data entry system that would enable responsible parties to submit information in a structured manner. Structured data entry is necessary to enable the clinical trials data bank to accommodate the full range of study design and data types common or emerging in the clinical trials community, while simultaneously ensuring that all required data elements are provided; optimize the presentation of submitted data, including adverse event information, for various types of users, including those with less experience in interpreting information about the relative risks and benefits associated with particular interventions; and allow for efficient search capabilities, including searching by the data fields specified by the statute. Structured data entry requires a responsible party to submit data in pre-specified fields. As a result, a data bank can be created to manage all of the information from different trials at the level of the individual fields. This approach contrasts with the collection of heterogeneous, free-text documents

(e.g., PDF documents). In the latter situation, NLM would be unable to make the displays consistent or create and populate a data bank that would support the search capabilities specified by section 402(j) of the PHS Act and needed to use the data bank. The development of a structured results data bank was consistent with the design of the existing ClinicalTrials.gov registry data bank, which launched more than seven years before the passage of FDAAA.

In the spring of 2008, we announced in the **Federal Register** the beginning of an iterative process to advance development of a data bank to support the submission of the results information specified by section 402(j)(3)(C) of the PHS Act (73 FR 29525, May 21, 2008). Any user with a ClinicalTrials.gov account (i.e., an account for submitting registration information via the ClinicalTrials.gov Protocol Registration System, or PRS) was subsequently able to enter real or test data into the test system and view the resulting clinical trial records. Mechanisms for data entry and display and descriptions of individual data items were refined in response to comments from users of the test system, leading to the launch of an operational results submission system in September 2008. Further improvements to the system were made based on the experience of responsible parties submitting comments and from the Agency in reviewing results information submitted under section 402(j)(3)(C) of the PHS Act.

The operational system for results information enables responsible parties to submit required information. Because section 402(j)(3)(C)(i) of the PHS Act calls for the information on demographic and baseline characteristics of the study sample to include information on ''the number of patients who dropped out of the clinical trial and the number of patients excluded from the analysis, if any,'' the operational system separates the collection of information about participant flow (i.e., the number of subjects who started the clinical trial, completed the clinical trial, and were excluded from the analysis or dropped out of the trial) from demographic and baseline data. Our review of a large number of clinical trials determined that the only demographic data consistently collected across all of these clinical trials were age and gender. The operational system therefore collects information about age and gender, facilitates submission of other commonly collected demographic data such as race or ethnicity, and allows definition and submission of other demographic data from the clinical trial. Responsible parties may define and submit information on baseline characteristics that are most relevant to the particular clinical trial.

The operational results submission system that became available in September 2008 also supported the voluntary submission of information about serious adverse events and other frequent adverse events. Responsible parties were able to voluntarily submit information on serious and other adverse events in a manner largely consistent with the statutory default provisions in section 402(j)(3)(I)(iii)(I) and (II) of the PHS Act. Prior to implementing the capability to submit adverse event information, we found through our consultations and discussions that, although regulatory requirements and standards exist for the reporting of adverse events experienced by participants during a clinical trial, there is no standard approach for summarizing adverse event data from an entire clinical trial for purposes of inclusion in a public data bank. We viewed the process of enabling voluntary submission of summary adverse event information in the initial results submission system, prior to the statutory default provisions taking effect, as a means of determining whether the statutory default provisions would represent a feasible and ''best method'' of including adverse event information, consistent with section 402(j)(3)(I)(i) of the PHS Act. To help the Agency determine whether the 5 percent threshold specified in section 402(j)(3)(I)(iii)(II) of the PHS Act was an appropriate cap for information about frequent adverse events, we permitted data submitters to submit summary data on non-serious adverse events using a threshold other than 5 percent . They could choose any higher or a lower threshold.

The Agency did not promulgate regulations implementing the best method for including adverse events within 18 months of the date of enactment of FDAAA due to the time needed to evaluate different strategies for submitting adverse event information. As a result, the statutory default provisions in section 402(j)(3)(I)(iii) of the PHS Act for submitting adverse events information were implemented in the data bank on September 27, 2009. Responsible parties submitting results information were required to submit ''a table of serious anticipated and unanticipated adverse events, grouped by organ system, with number and frequency of such event in each arm of the clinical trial'' and ''a table of anticipated and unanticipated adverse events that are not included in the [serious adverse event table] that exceed a frequency of 5 percent within any arm of the clinical trial, grouped by organ system, with number and frequency of such event in each arm of the clinical trial'' (See sections 402(j)(3)(I)(iii)(I) and (II) of the PHS Act.) While there is a requirement to submit non-serious adverse events with a frequency of 5 percent or more in any arm, responsible parties may submit data voluntarily on non-serious adverse events with a threshold of less than 5 percent. The system also accommodates the voluntary submission of information indicating the methodology used for assessing adverse events (systematic versus non-systematic) and the time period during which adverse event information was collected.

We and the community of responsible parties have gained considerable experience with results submission, including adverse event information, since September 27, 2008, when results submission was required by section 402(j)(3)(C) of the PHS Act for certain applicable clinical trials. As of April 24, 2013, summary results for about 8,700 clinical trials had been submitted by responsible parties, processed by the Agency and made publicly available in the data bank. Based on this experience, we have refined the design of the data entry system, developed instructional materials to assist responsible parties in preparing data for submission, and refined procedures for processing submitted information. Responsible parties have improved their procedures for collecting and preparing data for submission to the data bank. We have drawn upon this considerable experience and the lessons learned in formulating this proposed rule.

III. Overview of Proposed Rule

A. Structure of proposed rule

We propose to add a new Part 11 to Title 42 of the Code of Federal Regulations (CFR) to implement the statutory requirements set forth in section 402(j) of the PHS Act. This proposed rule is divided into four major subsections:

- Subpart A outlines the general provisions of this proposed rule. It specifies the purpose of the rulemaking, to whom this proposed rule applies, requirements for submission of truthful information, the form and manner of submitting information to the data bank at *ClinicalTrials.gov,* and definitions specific to this part.
- Subpart B specifies requirements for registering an applicable clinical

trial. It specifies who must register trials, which trials must be registered, when registration information must be submitted, where registration information must be submitted, what registration information must be submitted, and when submitted registration information will be posted.

- Subpart C specifies requirements for submission of results information, including adverse event information, for applicable clinical trials of drugs (including biological products) and devices that have been approved, licensed, or cleared by FDA and for applicable clinical trials of drugs (including biological products) and devices that have not been approved, licensed, or cleared by FDA. It specifies who must submit clinical trial results information; for which trials such information must be submitted; when such information is due, including provisions for delayed results submission and requesting extensions; where such information must be submitted; what clinical trial results information must be submitted; when such information will be posted; and the circumstances under which the NIH will grant a waiver of the results submission requirements.
- Subpart D specifies additional required submissions of information to the data bank, including the timing of updates and corrections to submitted information and mandatory submission of clinical trial information in the interest of public health for certain applicable clinical trials that otherwise would not be subject to the registration and results submission requirements of this part. It also specifies requirements affecting the voluntary submission of information about clinical trials for which the submission of registration and results information is not otherwise required under this part.

Elements that are required to be considered in the rulemaking under section 402(j)(3)(D) of the PHS Act are addressed in the relevant subpart. For example, proposals related to results submission for applicable clinical trials of unapproved, unlicensed, or uncleared products are contained in subpart C (Results Submission), while those related to the updating of submitted clinical trial information are contained in subpart D (Additional submissions of clinical trial information).

B. General considerations in the rulemaking

As stated in section 402(j)(2)(A)(i) of the PHS Act, the data bank is intended ''to enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials.'' In addition to satisfying this obligation, we believe it is essential to continue to provide a comprehensive and robust data bank to encourage broad and widespread registration and submission of results of clinical trials and other types of clinical studies. Comprehensive registration and results submission for such studies is consistent with NLM's statutory obligations to disseminate information concerning research and to promote public health. It can provide information to potential research participants, reduce inadvertent and unnecessary duplication of clinical studies, help journal editors detect incomplete descriptions of the results of specific clinical trials, and allow analysis of the results of multiple clinical trials of the same or similar interventions, thus providing regulators, scientists, health professionals, and the public with more information regarding the potential benefits and harms of different interventions.

We also believe it is essential for the data bank to serve a wide variety of users. While the public is the ultimate beneficiary of the data bank and the information contained in it, the overall public benefit will derive from access to and use of the data by different constituencies within the general public. We believe that clinical researchers, systematic reviewers, experts in evidence-based medicine, regulators, drug and device manufacturers, human subjects protection review boards (including institutional review boards (IRBs)), healthcare providers, disease and patient advocacy groups, students and educators, and patients and their family members may be able to use the available information to learn more about FDA-regulated products, to increase the efficiency of drug and device development processes, and to improve the design and conduct of clinical research studies, among other uses.

Building a data bank that serves multiple users with varying degrees of expertise in analyzing and interpreting clinical trial data means that not all of the collected information will necessarily be easy for all users to interpret. Some members of the general public, for example, may have difficulty interpreting certain results information, including adverse event information, or putting it into context. To address such concerns, we currently provide and, consistent with sections 402(j)(3)(A)(ii)(I) and (II) of the PHS Act, intend to expand links to additional explanatory material, including general information about clinical trials; publicly available FDA, NIH, and systematic review information about the products being studied; NIH information about the conditions that are the focus of the clinical trial; peer-reviewed journal articles summarizing the results of clinical trials; and specified FDA information about the clinical trial. We intend to develop improved ways of displaying submitted clinical trial information and enabling users to search for it, as we continue to gain experience with the operational system and to consult with experts in risk communications and clinical trial research. We also expect to solicit public input on this topic using a variety of mechanisms.

It is important to note that this proposed rule does not impose any requirements for the design or implementation of a clinical trial or for the collection of information during a clinical trial. This proposed rule specifies requirements for submitting information that describes a clinical trial as it was designed, conducted, and analyzed. The proposed data submission requirements are intended to accommodate current and emerging practices in design and implementation of clinical trials. We expect that the information required to be submitted to ClinicalTrials.gov will have been developed and collected prior to the time it must be submitted to the data bank and for reasons distinct from compliance with section 402(j) of the PHS Act and this proposed rule. In general, required information would have been included in standard clinical trial documentation (e.g., the protocol), collected during the course of the clinical trial (e.g., the types of adverse events specified in the protocol), or produced by the analysis that was specified in the protocol (e.g., outcome measures and statistical tests).

C. Key issues considered in this proposed rule

In developing this proposed rule, we considered a number of issues associated with the implementation of the statutory requirements for registration under section 402(j)(2) of the PHS Act and results submission under section 402(j)(3)(C) of the PHS Act and with the expansion of the data bank via rulemaking, as specified in section 402(j)(3)(D) of the PHS Act. We discuss these issues in this section of the preamble and reflect their implementation in the specific proposals described in section IV. We welcome comments on the Agency's proposals for addressing each of these topics in this proposed rule and additional information that might inform their implementation.

1. Elaboration of statutory definitions

Section 402(j)(1)(A) of the PHS Act defines a number of terms that are essential to implementation of the statute and the development of this proposed rule. Among the most important are the terms applicable clinical trial and responsible party, which are key elements in defining the set of trials that are subject to the registration and results submission requirements of section 402(j) of the PHS Act and the individuals or entities that are responsible for submitting the required information, respectively.

(a) Applicable clinical trial. Section 402(j)(1)(A)(i) of the PHS Act defines the term applicable clinical trial as either an applicable device clinical trial or an applicable drug clinical trial, both of which are defined in section 402(j)(1)(A) of the PHS Act. Section 402(j)(1)(A)(ii) defines applicable device clinical trial as ''(I) a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the [FD&C Act] against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and (II) a pediatric postmarket surveillance as required under section 522 of the [FD&C Act].'' Section 402(j)(1)(A)(iii) defines an applicable drug clinical trial as a ''controlled clinical investigation, other than a phase I clinical investigation, of a drug subject to section 505 of the [FD&C Act] or to section 351 of [the PHS Act,]'' where ''clinical investigation'' has the meaning given in 21 CFR 312.3 or any successor regulation and phase I has the meaning given in 21 CFR 312.21 or any successor regulation.

This proposed rule, in § 11.10, adopts the statutory definitions of all three of these terms, replacing the phrase ''phase I'' in the definition of applicable drug clinical trial with the phrase ''phase 1'' to be consistent with the numbering scheme used in FDA regulations at 21 CFR 312.21. Because of the significance of these terms in determining which clinical trials are subject to the provisions of this proposed part, we include in section IV.A.5 of this preamble an extensive elaboration of their meanings, interpreting each component part of the definitions in a way that is consistent with existing use of the stated terms in relevant FDA regulations, which may differ from current usage in some segments of the clinical research community. We also propose in § 11.22(b) an approach for using a limited set of registration data elements to determine whether a particular study meets the definition of an applicable clinical trial. We believe there is significant advantage in having a simple mechanism for a responsible party to determine, based on a standard set of factors, whether a study meets the definition of an applicable clinical trial. Such a mechanism would reduce uncertainty among responsible parties about their data submission obligations under section 402(j) of the PHS Act and reduce their burden in making such a determination.

A key consideration in the elaborations and the mechanism for determining whether a study meets the definition of an applicable clinical trial is defining what it means for an applicable drug clinical trial to be ''controlled'' or for an applicable device clinical trial to compare an intervention against a control. We explain our interpretation of these phrases in the preamble, and we include in § 11.10 of this proposed rule a definition of the term ''control or controlled.'' Our proposed definition is consistent with the types of controls recognized by FDA in its regulations for clinical trials of drugs and devices (21 CFR 314.126(b)(2)(i)–(v) and 21 CFR 860.7(f)(1)(iv)(a)–(d)) in that it includes both concurrent controls, as would be used in trials with multiple arms, and non-concurrent controls, as may be used in single-arm trials that are expressly designed to compare the effect of an intervention to an historical control or to baseline data, e.g., with participants serving as controls. It is broader than the FDA definitions of ''adequate and well controlled'' in 21 CFR 314.126(b) and ''well controlled'' in 21 CFR 860.7(f) in that it does not imply a judgment about the adequacy or appropriateness of the control and the study design.

Based on this definition, we would consider any clinical trial with multiple concurrent arms to be controlled for purposes of determining whether it is an applicable clinical trial subject to this proposed Part. We would also consider some single-arm clinical trials to be controlled. Such trials include single-arm trials of FDA-regulated products that, as specified in their protocols, intend to evaluate an effect by comparing measures taken after an intervention to baseline measures taken from the participants prior to the intervention. Many of these studies have explicitly defined ''change from baseline'' measures identified in their protocols, i.e., they are designed to compare a measure taken after an intervention to the participant's state prior to the intervention. Other single-arm trials that we would consider controlled include, for example, studies with an identified measure of ''response rate'' or measures in which the state prior to or without the intervention can be assumed (e.g., studies in conditions that do not resolve without intervention, such as cancer).

We propose in § 11.28 that a responsible party who registers a single-arm trial indicate whether the trial protocol or statistical analysis plan specifies a control as defined in this part. While plans for analyzing collected data may change during the course of a study, we believe that the requirement that the control be specified in the protocol or statistical analysis plan will improve consistency in the interpretation of this requirement across trials. We considered requiring greater specification about the type of control, if any, used in the single-arm study, e.g., historical control (including subjects as their own control), but believe our proposed approach provides the information necessary for identifying applicable clinical trials while minimizing the burden on responsible parties. We propose in § 11.22(b) to use the information submitted by the responsible party to determine whether a trial meets the definition of an applicable clinical trial.

We invite comments on our proposed approach for identifying single-arm trials that would be considered controlled and on alternative ways to identify such trials. In particular, we invite comments on whether there are other specific, objective features of clinical trials that could serve as the basis for differentiating between single-arm studies that are and are not controlled. We also invite comments on and information about, the types of single-arm trials that meet the other criteria for an applicable clinical trial and do or do not meet our proposed definition of controlled.

(b) Responsible party. Section 402(j)(1)(A)(ix) defines the responsible party with respect to a clinical trial of a drug or device as: ''(I) the sponsor of the clinical trial (as defined in . . . 21 [CFR 50.3] . . . (or any successor regulation)); or (II) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements . . . [of this part] for the submission of clinical trial information.'' We adopt this definition with minor, non-substantive

modifications in § 11.10 of this proposed rule.

Given the significance of the role that the responsible party plays in complying with section 402(j) of the PHS Act, we elaborate on the meaning and interpretation of this term in section IV.A.5 of this preamble. We have codified parts of the elaboration of the definition of responsible party in proposed § 11.4(c), which specifies procedures for determining the responsible party. We have also included a definition of the term sponsor in proposed § 11.10.

2. Modifications and Additions to the Elements of Clinical Trial Registration Information

The clinical trial registration information required by section 402(j)(2)(A)(ii) of the PHS Act includes 25 specific data elements grouped into 4 categories: Descriptive information, recruitment information, location and contact information, and administrative information. Additionally, section 402(j)(2)(A)(iii) of the PHS Act authorizes the Secretary, by regulation, to modify the statutory requirements for clinical trial registration information if a rationale is provided as to ''why such a modification improves and does not reduce'' such information. Proposed § 11.28 lists the clinical trial information that we propose to require at the time of registration. The definitions of specific data elements are provided in proposed § 11.10(b). For the most part, the proposed list of data items conforms to the list of items enumerated in section 402(j)(2)(A)(ii) of the PHS Act, restating, and, in many instances, clarifying the statutory data items. However, this proposed rule includes certain modifications and additions to the data items listed in 402(j)(2)(A)(ii) of the PHS Act that we conclude improve the clinical trial information available to the public and implement the requirements of the statute. We do not believe that any of the proposed modifications and additions reduces the clinical trial information available to the public. As further explained in section IV.B.4 of this preamble, a number of the proposed modifications and additions to clinical trial registration information listed in section 402(j)(2)(A)(ii) of the PHS Act are not new to some responsible parties and other users of the data bank who submitted information to ClinicalTrials.gov prior to FDAAA; many of the data elements are the same or similar to those collected in ClinicalTrials.gov prior to enactment of FDAAA.

Our proposed modifications and additions to clinical trial registration information take the following general forms.

(1) Structuring data entry for registration data elements to help the public use the data bank and compare entries, as required by section 402(j)(2)(B)(iv) of the PHS Act. We believe structured data entry for registration data elements helps satisfy the requirement at 402(j)(2)(B)(iv) to ''ensure that the registry data bank is easily used by the public, and that entries are easily compared,'' because it will enable users to search the data bank using the criteria listed in section 402(j)(2)(B)(i) of the PHS Act and will prompt responsible parties to submit complete and accurate information. We therefore propose to require responsible parties to enter defined components of certain data elements, such as study design, outcome measure, and IND or IDE number. For example, in § 11.10(b)(35), we propose to define the Food and Drug Administration IND or IDE number, a data element expressly required to be submitted at the time of registration by section 402(j)(2)(A)(ii)(IV)(cc) of the PHS Act (therein referred to as the ''IND/IDE protocol number'') to include the name of the FDA center that issued the IND or IDE (e.g., the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), or the Center for Devices and Radiological Health (CDRH)); the IND or IDE number; and any serial number that has been assigned by the sponsor to that filing. We believe these three components are necessary to provide complete information about IND/IDE number.

(2) Additions to allow effective implementation of, or compliance with, other provisions of section 402(j) of the PHS Act. For example, this proposed rule in § 11.28(a)(1)(xv) requires information about whether a product under study in a clinical trial is manufactured in the U.S. or one of its Territories because this information is necessary in some situations to determine whether or not a clinical trial meets the definition of an applicable clinical trial or would be considered a voluntary submission under section 402(j)(4)(A) of the PHS Act.

(3) Additions to improve the quality and consistency of information available in the data bank and enabling users to better search for, retrieve, and understand it. For example, in § 11.28(a)(1)(xi) of this proposed rule, we propose that responsible parties submit other current and former names for interventions studied in a clinical trial (if other such names exist) to help identify duplicative trial registrations and assist users in finding clinical trials for interventions that might be registered under different names (e.g., the name of the chemical compound, the brand name of an approved product, or an alias used during pre-marketing studies).

(4) Addition to indicate the ethical and scientific review status of the clinical trials listed in the data bank. We believe that it is essential that patients and practitioners searching ClinicalTrials.gov for information about clinical trials retrieve information on whether a clinical trial registered in ClinicalTrials.gov is undergoing or has undergone review procedures with respect to ethical and scientific considerations. A small number of applicable clinical trials may not be required by applicable law, regulation, and/or institutional policy to seek approval from a human subjects protection review board (e.g., if a waiver has been provided, the clinical trial is determined to be exempt in accord with applicable law and regulation, or the clinical trial is not subject to laws, regulations, or institutional policies that require review by a human subjects protection review board). In such cases, the proposed rule would require responsible parties to indicate that human subjects protection review board approval is not required by applicable law, regulation, or institutional policy. We recognize that provision of information on human subjects review status cannot guarantee the quality of a clinical trial or the safety of human subjects who are enrolled in it. Nevertheless, we believe that requiring responsible parties to indicate whether a clinical trial registered in ClinicalTrials.gov is undergoing or has undergone review by a human subjects protection review board may provide some measure of assurance in most situations.

We invite comments on our proposed modifications and additions to the data elements of clinical trial registration information, including the benefits and burdens associated with structuring certain registration data elements.

3. Posting of Registration Information for Applicable Device Clinical Trials

Section 402(j)(2)(D) of the PHS Act establishes the timelines for posting clinical trial registration information submitted by responsible parties in the data bank. For applicable drug clinical trials, section 402(j)(2)(D)(i) of the PHS Act requires NIH to post publicly clinical trial registration information not later than 30 days after it has been

submitted. For applicable device clinical trials of devices that previously have been approved or cleared by FDA, section 402(j)(2)(D)(ii)(II) of the PHS Act requires that clinical trial registration information be posted not later than 30 days after clinical trial results information is required to be posted by NIH. As discussed in detail in section IV.B.5(b) of this preamble, NIH has interpreted this provision as allowing NIH to post clinical trial registration information for applicable device clinical trials of these devices as soon as practicable. For applicable device clinical trials of devices that have not previously been approved or cleared, NIH intends that, consistent with section 402(j)(2)(D)(ii)(I) of the PHS Act, clinical trial registration information will be posted not earlier than the date on which FDA approves or clears the device and not later than 30 calendar days after the date of such approval or clearance.

While postponing the posting of clinical trial registration information for applicable device clinical trials for a device that previously has not been approved or cleared may protect the commercial interests of device manufacturers, there are a number of situations in which those who conduct such clinical trials may prefer to make such information publicly available in the data bank prior to the time frames allowed by section 402(j) of the PHS Act and this rulemaking. For example, based on experience to date, we believe that some sponsors and principal investigators prefer to make their registration information publicly available in the data bank because this would be an easy way to meet the ICMJE policy [Ref. 10], which requires public registration in a data bank prior to enrollment of the first patient as a precondition for consideration for publication. Others prefer to make registration information available to the public to assist with or expand upon efforts to recruit potential human subjects for a trial. In other cases, responsible parties might wish to make some of the registration information available to demonstrate to others (e.g., a funding organization or the sponsor) that a clinical trial has, in fact, been registered as required by section 402(j) of the PHS Act and this proposed regulation.

We considered, but do not propose, two potential mechanisms for addressing these situations: (1) Allowing a responsible party to give voluntarily the NIH permission to release clinical trial registration information for an applicable device clinical trial of a device that previously has not been approved or cleared for public posting in the data bank, and (2) allowing any individual or entity to whom the responsible party provides the NCT number for such a trial (i.e., the unique identifier that is assigned to a trial upon registration in the data bank) to access a very limited set of data sufficient to verify that the clinical trial of interest has been registered, but without revealing substantive information about the clinical trial, such as the focus of the clinical trial or the products involved. However, section 402(j)(2)(D)(ii) of the PHS Act provides that the ''Director of NIH shall ensure that clinical trial information for an applicable device clinical trial of an unapproved or uncleared device submitted in accordance with . . . [section 402(j)(2) of the PHS Act not be] posted publicly . . .'' before approval or clearance. Because neither of the mechanisms appears to be permissible under the statute, we have not proposed implementing either of these mechanisms in this rulemaking. We invite comments from the public on how, given the statutory language, the Agency may address the concerns of sponsors and responsible parties who wish to have clinical trial registration information for applicable device clinical trials of devices that previously have not been approved or cleared made publicly accessible in ClinicalTrials.gov when the responsible party so chooses.

4. Application of Rule to a Pediatric Postmarket Surveillance of a Device That Is Not a Clinical Trial

In section 801(c), FDAAA requires the Secretary of HHS to issue guidance on how section 402(j) of the PHS Act applies to a pediatric postmarket surveillance of a device that is not a clinical trial. Section 402(j)(1)(A)(ii)(II) of the PHS Act defines the term applicable device clinical trial to include ''a pediatric postmarket surveillance as required under section 522 of the [FD&C] Act.'' This proposed rule in § 11.10 defines ''pediatric postmarket surveillance of a device'' as ''the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information conducted under section 522 of the [FD&C] Act about a marketed device that is expected to have significant use in patients who are 21 years or younger at the time of diagnosis or treatment. A pediatric postmarket surveillance of a device may be, but is not always, a clinical trial.''

FDA may order a pediatric postmarket surveillance of a device under section 522 of the FD&C Act for any class II or class III device, as defined by 21 U.S.C. 360c(a) and 21 CFR 860.3, meeting any of the following criteria: Its failure would be reasonably likely to have serious adverse health consequences; it is expected to have significant use in pediatric populations; it is intended to be implanted in the body for more than 1 year; or it is intended to be a life-sustaining or life-supporting device outside a device user facility. (See 21 U.S.C. 360l(a).) Pediatric postmarket surveillances under section 522 of the FD&C Act can take various forms, including a detailed review of the complaint history and the scientific literature, non-clinical testing, observational studies, and controlled clinical trials [Ref. 25].

Because section 402(j)(1)(A)(ii)(II) of the PHS Act defines the term ''applicable device clinical trial'' to include pediatric postmarket surveillances of a device, such surveillances must be registered, and clinical trial results information must be submitted for them. Our proposed approach for applying the registration requirements to a pediatric postmarket surveillance of a device that is not a clinical trial is described in proposed § 11.28(b). Our proposed approach for applying the results submission requirements to a pediatric postmarket surveillance of a device that is not a clinical trial is described in proposed § 11.48(b). A pediatric postmarket surveillance of a device that is a clinical trial would be subject to the general requirements of this proposed rule, including the clinical trial registration and results submission requirements in proposed §§ 11.28(a) and 11.48(a), respectively. Further elaboration of these proposals is contained in section IV.B of this preamble.

5. Submission of Results Information for Applicable Clinical Trials of Unapproved, Unlicensed, or Uncleared Products

(a) General requirements and rationale. Section 402(j)(3)(D)(ii)(I) of the PHS Act requires the submission of results information for: (1) Each applicable drug clinical trial for a drug that is approved under section 505 of the FD&C Act or licensed under section 351 of the PHS Act; and (2) each applicable device clinical trial for a device that is cleared under section 510(k) of the FD&C Act or approved under section 515 or 520(m) of the FD&C Act. By contrast, section 402(j)(3)(D)(ii)(II) of the PHS Act requires that the Secretary establish, through regulation, whether or not results information must be submitted for applicable clinical trials of unapproved, unlicensed, or uncleared

products, whether or not approval, licensure, or clearance was sought. If the Secretary requires, by regulation, the submission of results information for unapproved, unlicensed, or uncleared products, then section 402(j)(3)(D)(iv)(III) of the PHS Act authorizes the Secretary to determine, by regulation, ''the date by which such clinical trial information shall be required to be submitted,'' taking into account (a) the process under section 402(j)(3)(E)(iii) of the PHS Act for ''delayed submission of results with certification'' when approval, licensure, or clearance is sought; and (b) whether there should be a delay of submission when approval, licensure, or clearance will not be sought.

Pursuant to our authority under section 402(j)(3)(D)(ii)(II) of the PHS Act, we have decided to propose that results information be submitted for applicable clinical trials of drugs and devices that are not approved, licensed, or cleared by FDA, regardless of whether approval, licensure, or clearance is sought. In addition, pursuant to our authority under section 402(j)(3)(D)(iv)(III) of the PHS Act, we propose deadlines for submitting this results information that, as required by statute, take into account both the certification process under section 402(j)(3)(E)(iii) of the PHS Act for delayed submission of results when approval, licensure, or clearance is sought and whether there should be delayed submission of results when approval, licensure, or clearance will not be sought. As discussed in section III.D of this preamble, these proposals would apply to applicable clinical trials of unapproved, unlicensed, or uncleared products that reach their completion dates on or after the effective date of this rule, as well as certain applicable clinical trials of unapproved, unlicensed, or uncleared products that reach their completion dates prior to the effective date of the rule.

We believe our proposal to require results submission for applicable clinical trials of unapproved, unlicensed, or uncleared products is in furtherance of the express statutory purpose of the expanded data bank, which states that the Secretary shall expand the registry and results data bank ''[t]o provide more complete results information and to enhance patient access to and understanding of the results of clinical trials.'' (See section 402(j)(3)(D)(i) of the PHS Act.) In developing our proposal, we considered a number of factors, many of which were raised at the Public Meeting [Ref. 1], notably the potential public health benefits of timely disclosure of results information for clinical trials of drugs that are not approved, biological products that are not licensed, and devices that are not approved or cleared; the potential effects of disclosure on the competitive advantage of drug and device manufacturers, including incentives to invest in the development of new products intended to improve public health; and other results submission requirements and policies (e.g., those of the EMA). Other considerations include the relative burden on the responsible party of submitting results for clinical trials of unapproved drugs, unlicensed biological products, and unapproved or uncleared devices, the date by which results must be submitted, and practical issues of implementation and compliance.

The Agency finds compelling the arguments in support of a requirement to submit the results of applicable clinical trials of unapproved, unlicensed, or uncleared products. The availability of such information in ClinicalTrials.gov could have several potential public health benefits. Systematic disclosure of results of applicable clinical trials of unapproved, unlicensed, or uncleared products would mitigate the bias in information available to the public about studied medical products that stems from selective disclosure of clinical trial results [Ref. 26]. Currently, sponsors, researchers, and product manufacturers often voluntarily and selectively release to the public partial information about the results of specific studies, including those of unapproved, unlicensed, or uncleared products, via scientific publications and abstracts, press releases, and other announcements. Requiring the submission of results of applicable clinical trials of unapproved, unlicensed, or uncleared products in a systematic and standardized format would provide a more current and complete picture of results of clinical trials of FDA-regulated products, therefore reducing a potential source of bias.

The public availability of results information about trials of unapproved, unlicensed, and uncleared drugs (including biological products) and devices would also help protect the safety of participants who volunteer to be in clinical trials by reducing the likelihood that people will unknowingly design, approve, or participate in clinical trials that are unnecessary (e.g., because similar clinical trials have already been conducted but not published), or that are potentially harmful (e.g., because similar interventions have been shown to be harmful or ineffective in previous, unpublished clinical trials). It would also help potential human subjects make more informed decisions about participating in a clinical trial by providing them and their care providers with information about the results of a broader set of clinical trials of various interventions that have been studied for a disease or condition of interest. Investigators and human subjects protection review boards that already have access to unpublished information from the sponsor of a clinical trial or the manufacturer of a drug or device would have access via ClinicalTrials.gov to information about other clinical trials of similar unapproved, uncleared, or unlicensed products that might help them in designing or considering the potential risks and benefits of participation in a clinical trial.

In addition, submission of results of clinical trials of unapproved, unlicensed, or uncleared products would broaden the evidence base for systematic reviewers and others involved in assessing the benefits and harms of classes of drugs and devices. Many clinical trials compare unapproved, unlicensed, or uncleared drugs and/or devices with approved, licensed, or cleared drugs and/or devices, and the submission of results of such clinical trials could increase access to additional information about the marketed products for their approved, licensed, or cleared uses. In addition, many unapproved, unlicensed, or uncleared products are similar to products that are approved, licensed, or cleared and in the marketplace. This is particularly true of the unapproved, unlicensed, or uncleared versions of products that are studied in clinical trials that contribute to the evidence base for subsequent approval, licensure, or clearance of a different version of the product. Preliminary or alternative versions of a drug, for example, may differ from the approved or licensed version in dose, form, or inactive ingredients, even if they contain the same active ingredient(s). Results of clinical trials of unapproved products could therefore enhance the knowledge base for understanding classes of products.

There is also a compelling ethical rationale for making available to the public the results from clinical trials that involve human subjects, regardless of the approval status of the product. Part of the agreement made with human subjects who agree to participate in clinical trials is that knowledge that is obtained in the clinical trial will be available for use in advancing biomedical science [Ref. 27].

Submission and subsequent posting of the results of applicable clinical trials of unapproved drugs, unlicensed biological products, and unapproved or uncleared devices to ClinicalTrials.gov that reach their completion dates on or after the effective date of a final rule would help to achieve that goal, especially for clinical trials for which results are never published in the scientific literature.

We also are aware of ongoing regulatory efforts by the EMA to make results of clinical trials of drugs conducted within the EU available in a publicly accessible data bank, regardless of the approval status of the drug [Ref. 28, 29, 30]. Already, all clinical trials of drugs performed within the EU are registered in EMA's EudraCT database, with information on phase 2, 3, and 4 clinical trials and all pediatric clinical trials made public through the EU Clinical Trials Register (*https://www.clinicaltrialsregister.eu/*). In June 2010, EMA issued for public comment the draft implementing technical guidance on the EudraCT results data bank. The technical guidance specifies summary results information that would be submitted to the data bank for public posting. The specified summary results information differs from the detailed information that would be submitted to EMA as part of a Marketing Authorization Application. As noted in that document, EMA has worked with ClinicalTrials.gov staff to harmonize common data elements used by the two results data banks, which we view as a way of simplifying the process of submitting results to EudraCT and ClinicalTrials.gov, for those trial that are required to submit results to both data banks. Many clinical trials that would be subject to EMA regulations requiring the disclosure of clinical trial results would likely be applicable clinical trials subject to section 402(j) of the PHS Act. We believe that if clinical trial results information is available via another publicly accessible data bank (such as EudraCT), a number of the concerns that have been expressed about disclosure in ClinicalTrials.gov would no longer be applicable. The use of common data elements would promote harmonization of results information in EudraCT and ClinicalTrials.gov and simplify data submission for clinical trials that would be summarized in both databases.

We recognize that the posting of results information about clinical trials of unapproved, unlicensed, and uncleared products presents special challenges. Such information would be accessible to care providers and their patients and would describe uses of products that are not approved, cleared, or licensed. Even for approved, cleared, or licensed uses the posted result information would contain information that is not included in approved labeling and that requires further interpretation for understanding potential risks and benefits. We believe that the results information from any individual clinical trial should be considered not on its own, but in the context of the broader set of information available about the product and alternative products. In keeping with current practice, we intend to establish links from clinical trial records in ClinicalTrials.gov additional sources of information, including but not limited to the FDA and NIH information specified in section 402(j)(3)(A)(ii) of the PHS Act (we would indicate that the links were added by the NIH and not by the responsible party). As discussed further in section III.C.11, we would also provide information to assist users in better understanding and interpreting the information available in ClinicalTrials.gov, including materials that describe the general purpose and content of the data bank, the limitations of the data presented, and cautions that the information should be used in conjunction with advice from healthcare professionals.

We believe that all of these benefits can be best achieved by requiring the submission of results information for all applicable clinical trials involving unapproved, unlicensed, or uncleared products, regardless of whether FDA approval, licensure, or clearance is sought. Limiting results submission to those applicable clinical trials of unapproved, unlicensed, or uncleared products for which product development has been abandoned by industry would minimize industry concerns about disclosing potentially valuable information to competitors, but would do little to address concerns about bias in the disclosure of information. Considerable information of potential scientific, clinical, and public significance would still be hidden from public view and would continue to be unavailable for consideration by human subjects protection review boards in assessing proposed clinical trials, by individuals considering participation in them, or by other researchers who are planning similar clinical trials or clinical trials of similar products. Even if investigators and human subjects protection review boards have access to information from a clinical trial sponsor, they will not have access to the full range of unpublished results of other clinical trials that might be relevant to a clinical trial under consideration. We believe that concerns about commercial competitiveness resulting from disclosure of results information from clinical trials of products that are not approved, licensed, or cleared by the FDA can be mitigated by delaying the results submission deadline for applicable clinical trials of products that are still under development, as described later in this section. Indeed, disclosure of results information for clinical trials of products that are still under development could improve the efficiency of research and development (R&D) investments by reducing the likelihood that private companies, universities, and the U.S. Government will waste resources repeating studies of interventions that have already been conducted. In addition, limiting disclosure to applicable clinical trials of products for which product development has been abandoned would be difficult to administer because only the sponsor and/or manufacturer are in a position to determine that product development has been abandoned for all potential uses. Moreover, as noted by some industry commenters, product development is often suspended for periods of time before being resumed when company priorities change or a developmental product is transferred to another company. Information about unapproved products still in product development pipelines might therefore remain undisclosed for long periods of time, depriving the public of the benefits that could result from disclosure even in situations where non-disclosure might provide little commercial advantage.

We therefore propose, as authorized by section 402(j)(3)(D)(ii)(II) of the PHS Act and as specified in proposed § 11.42(a), to require submission of clinical trial results information for applicable clinical trials that reach their completion dates on or after the effective date of the rule and that involve a drug, biological product, or device that is not approved, licensed, or cleared for any indication, regardless of whether the sponsor seeks approval, licensure, or clearance. We believe that requiring this information to be submitted is consistent with the statute's stated purpose in expanding the registry and results data bank ''[t]o provide more complete results information and to enhance patient access to and understanding of the results of clinical trials.'' (See section 402(j)(3)(D)(i) of the PHS Act).

In considering the deadlines for submitting results information for applicable clinical trials of unapproved,

unlicensed, or uncleared products, as required by section 402(j)(3)(D)(iv)(III) of the PHS Act, the Agency recognized a need to balance several considerations namely: Commercial interests in protecting information about products under development, public health benefits of timely access to results information, the burden associated with submission of results information, and administrative burden. We also considered the statutory requirements of section 402(j)(3)(D)(iv)(III) of the PHS Act to take into account: (1) the certification process for delayed submission of results under section 402(j)(3)(E)(iii) of the PHS Act ''when approval, licensure, or clearance is sought'' for a product studied in an applicable clinical trial; and (2) ''whether there should be a delay of submission when approval, licensure or clearance will not be sought.''

As further described below, we propose to require results submission for applicable clinical trials involving unapproved, unlicensed, or uncleared products not later than 1 year after the completion date of the clinical trial, unless the responsible party submits a certification under section 402(j)(3)(E)(iii) of the PHS Act prior to that deadline indicating that initial approval, licensure, or clearance is being sought or may at a future date be sought.

Delayed submission of results of applicable clinical trials involving products that are unapproved, unlicensed, or uncleared would be permitted only if the responsible party certifies under section 402(j)(3)(E)(iv) of the PHS Act that the sponsor or manufacturer intends to continue with product development, meaning that it is either seeking, or may at a future date seek, initial approval, licensure, or clearance of the product under study in an applicable clinical trial. For applicable clinical trials of unapproved, unlicensed, or uncleared products, results submission may be delayed only if section 402(j)(3)(E)(iv) of the PHS Act applies. In determining whether section 402(j)(3)(E)(iv) of the PHS Act applies to a particular applicable clinical trial, we took into consideration the fact that section 402(j)(3)(D)(iv)(III)(aa) of the PHS Act indicates that the certification process under section 402(j)(3)(E)(iii) of the PHS Act applies ''when approval, licensure, or clearance *is sought*'' (emphasis added), whereas section 402(j)(3)(D)(iv)(III)(bb) of the PHS Act states that the Secretary shall determine, by regulation, ''whether there should be a delay of submission when approval, licensure, or clearance *will not be sought*'' (emphasis added). We consider these two provisions together to mean that delayed submission of results with certification is allowable if initial approval, licensure, or clearance is sought, meaning that the sponsor or manufacturer intends to continue with product development and thus either is seeking, or may at a future date seek, approval, licensure, or clearance. This proposed rule does not include a provision extending delayed submission when approval, licensure, or clearance will not be sought.

Delayed submission of results would not be available to a responsible party who either meets the criteria in section 402(j)(3)(E)(iv) of the PHS Act to certify but does not submit a certification prior to the deadline under the process set forth in section 402(j)(3)(E)(iii) of the PHS Act, or who does not meet the statutory criteria to submit a certification. In such instances, we propose that results be due not later than 1 year after the completion date, unless an extension for good cause is requested and granted under section 402(j)(3)(E)(vi) of the PHS Act. This deadline is consistent with the time frame in section 402(j)(3)(E)(i) of the PHS Act for submitting results information. Specifically with regard to applicable clinical trials of drugs (including, biological products) or devices for which approval, licensure, or clearance will not be sought, we interpret the phrase ''will not be sought'' to mean that the sponsor or manufacturer has no intention of developing a marketable product or otherwise has abandoned product development. For these trials, the Agency believes that the public benefits of disclosure of results information outweigh any private, commercial interests. We recognize that, in many cases, whether initial approval, licensure, or clearance is, or may at a future date be, sought is information that will be known only to the sponsor or manufacturer of the drug, biological product, or device and may not even be known to them at the time a clinical trial is completed, especially for an earlier stage trial, such as a phase 2 applicable drug clinical trial. Instead, the sponsor or manufacturer may know only that it intends to continue with product development, such as through the conduct of a subsequent clinical trial. Accordingly, the Agency needs a way to verify that the sponsor or manufacturer is seeking, or may at a future date seek, initial approval, licensure, or clearance. Therefore, as a condition of delaying results submission for unapproved, unlicensed, or uncleared products, we propose in § 11.44(c), to require the responsible party to certify that the sponsor or manufacturer intends to continue with product development and either is seeking, or may at a future date seek, approval, licensure, or clearance. See section 402(j)(3)(E)(iv) of the PHS Act. If the responsible party elects to submit a certification for delayed submission, it is the responsible party's obligation to verify that the particular applicable clinical trial meets the proposed § 11.44(c) criteria, as explained in this preamble. We recommend that if the sponsor has designated the PI as the responsible party under the process described under proposed § 11.4(c), the sponsor should be prepared to communicate with the responsible party to help ensure the accuracy of any certification that is made.

If after submission of a certification that section 402(j)(3)(E)(iv) of the PHS Act applies to a specific applicable clinical trial, the drug, biological product, or device studied in the applicable clinical trial becomes approved, licensed, or cleared for the indication studied in the applicable clinical trial, results information would be due 30 calendar days after approval, licensure, or clearance. If, after submission of a certification that section 402(j)(3)(E)(iv) applies to the applicable clinical trial, initial approval is no longer being sought (i.e., product development is abandoned), we likewise do not believe that continued delays in results submission are warranted, and we recommend that the responsible party should submit results information as soon as practicable.

Furthermore, we do not believe that a delay in submitting results for applicable clinical trials of unapproved, unlicensed, or uncleared products should be indefinite, enduring until a responsible party proactively asserts that product development has been abandoned or until the product is approved, licensed, or cleared. We therefore propose to limit the allowable delay period for results submission for applicable clinical trials of unapproved, unlicensed, or uncleared products to 2 years after the submission of a certification for delayed results submission. The certification would have to be submitted prior to the date on which results information would otherwise be due (e.g., 12 months after the completion date), and we would permit only one certification to be submitted for each clinical trial. Product development can extend over long periods of time and may even be suspended or remain inactive for significant periods of time, whether due to limited financing, changes in

corporate policy, revised strategic plans, or other reasons. While sponsors or manufacturers may find commercial advantage in protecting clinical trial results during this extended period, those advantages must be weighed against the disadvantages of denying access to results information to the research community, healthcare providers, and the public for an extended period.

The proposed 2-year time limitation reflects a balance between the need to protect competitive advantage and the desire for public access to clinical trial results. Within this time frame, a sponsor or manufacturer would often make a decision about whether to initiate another clinical trial or submit a marketing application or premarket notification to the FDA. A subsequent pre-market clinical trial of a drug would likely be an applicable clinical trial that would be registered at ClinicalTrials.gov, making public information about the sponsor's intention to pursue product development. The total delay in disclosure of results of up to 3 years after the completion date would provide sponsors with significant lead time in product development over potential competitors.

(b) Additional results information for applicable clinical trials of unapproved or uncleared devices. Once clinical trial results information is submitted, section 402(j)(3)(G) of the PHS Act requires public posting of that information no later than 30 days after the date of submission (See proposed § 11.52, which implements this statutory requirement). Thus, clinical trial results information for applicable clinical trials of both approved, licensed, and cleared, products and unapproved, unlicensed, and uncleared products will be publicly posted no later than 30 calendar days after submission. Section 402(j)(2)(D)(ii)(I) of the PHS Act requires the clinical trial information submitted upon registration of applicable device clinical trials of devices that have not previously been approved or cleared not be posted earlier than the date on which FDA approves or clears the device studied in the applicable clinical trial. (See section III.C.3. of this preamble.) Therefore the proposed timelines for submitting and publicly posting clinical trial results information in §§ 11.44 and 11.52 may result in the public availability of clinical trial results information for applicable device clinical trials for unapproved or uncleared devices before the information submitted during registration is posted for these same trials.

We believe that posting clinical trial results information without the corresponding public availability of certain descriptive information that is the same type of information that is included as part of registration would fail to provide the necessary context for understanding clinical trial results information and would significantly limit access to and understanding of posted results data. This is why journal articles and other reports of the results of clinical trials routinely include information about the disease or condition and interventions under study, the inclusion and exclusion criteria for participants, the location(s) of the trial, etc. Without such information, results data about patient demographics, outcomes, and adverse events would be uninterpretable and inaccessible. For example, patients and other users typically access clinical trial results by searching for (and retrieving) clinical trials with specific characteristics, e.g., that involve a particular intervention or type of intervention, study a particular disease or condition, recruit certain types of subjects, take place during a particular time period, are conducted in a specific location or particular facility, are sponsored by a particular organization, or match a title or identification number they have found in other public sources. This type of information is not included as part of clinical trial results information under proposed § 11.48(a) but is the same type of descriptive information submitted upon registration, e.g., Brief Title, Intervention Name, Study Start Date, Completion Date.

Similarly, to enhance their understanding of the clinical trial results, researchers, healthcare providers, patients and other users of ClinicalTrials.gov need information about the purpose of the study, its design, the intervention(s) studied, the types of subjects eligible to participate, the duration of the study, and the outcome measures. They need to know whether the clinical trial is completed, if data are still being collected for other outcome measures, or if the clinical trial was terminated prematurely. They need to understand whether information has been submitted for all anticipated outcome measures and corresponds to the outcome measures that the clinical trial was designed to achieve (or did the outcome measures change during the course of the study). They also need information to assist them in comparing results with the results of other clinical trials and with other publicly available information about a clinical trial of interest and other trials. They also need to know whether the clinical trial was reviewed for human subjects protection and who had authority over the conduct of the trial. In addition, they need to know who submitted the information and when it was last verified (i.e., to indicate whether it might be out of date). Such information is not readily available from submitted results information, but is the same type of descriptive information provided during registration, e.g., Primary Purpose, Study Design, Primary Outcome Measure(s), Secondary Outcome Measure(s), Eligibility Criteria, Overall Recruitment Status, Oversight Authorities, Human Subjects Protection Review Board Status, Responsible Party, by Official Title, and Record Verification Date (See proposed § 11.28(a).

Section 402(j)(3)(D)(i) of the PHS Act states that the purpose of granting the Secretary rulemaking authority to expand the results information in the data bank is ''[t]o provide more complete results information and to enhance patient access to and understanding of the results of clinical trials.'' We believe it would be extremely challenging for the public to understand clinical trial results information without having access to certain descriptive information that is the same type of information submitted during trial registration. Thus, to ''enhance patient access to and understanding of the results,'' it is necessary for patients to have access to this descriptive information when clinical trial results information is posted, not only for applicable drug clinical trials of both approved and unapproved drugs (See section 402(j)(2)(D)(i) and section IV.B.5 of this preamble), but also for applicable device clinical trials of both approved or cleared devices and unapproved or uncleared devices.

Section 402(j)(3)(D)(ii)(II) of the PHS Act grants the Secretary discretion in what can be required through rulemaking to be submitted as part of clinical trial results information for applicable device clinical trials of devices that have not been approved or cleared. Specifically, it allows the Secretary to require the submission of results information that is ''described in clause (iii).'' Clause (iii), or section 402(j)(3)(D)(iii) of the PHS Act, states that the regulations ''shall require, in addition to the elements described in [section 402(j)(3)(C)]. . .[s]uch other categories as the Secretary determines appropriate'' (section 402(j)(3)(D)(iii)(IV) of the PHS Act). Thus, for applicable device clinical trials of unapproved or

uncleared devices, the Secretary can require, through rulemaking, submission of not only those results that are required under section 402(j)(3)(C) of the PHS Act, but ''such other categories'' of information as the Secretary determines appropriate.

To ''enhance patient access to and understanding of the results of the clinical trials'' as required by section 402(j)(3)(D)(i) of the PHS Act, we interpret ''such other categories'' of results information for applicable device clinical trials of unapproved or uncleared devices to include, among other things, certain descriptive information that is the same type of information that was required to be submitted under section 402(j)(2)(A)(ii) of the PHS Act. Accordingly, we propose under § 11.48(a)(6) to require responsible parties to submit this descriptive information as part of clinical trial results information for applicable device clinical trials of unapproved or uncleared devices. Because this descriptive information would be defined as part of clinical trial results information, it would be posted no later than 30 calendar days after it has been submitted, pursuant to section 402(j)(3)(G) of the PHS Act. See proposed § 11.48(a)(6) and section IV.C.4(g) of this preamble for a list of proposed required data elements.

Requiring responsible parties for applicable device clinical trials of unapproved or uncleared devices to resubmit information they would have submitted previously to the data bank under proposed § 11.28(a), in order to comply with proposed § 11.48(a)(6), would be inefficient and impose an unnecessary burden on responsible parties. It would also introduce the possibility that information provided at the time of results submission would be inconsistent with the information provided at the time of registration and require the Agency to perform a second quality review of information submitted at registration. To promote efficiency and lessen the burden on responsible parties, we propose to require these responsible parties to fulfill the proposed requirement under § 11.48(a)(6) by affirming in the data bank when submitting clinical trial results information that they are submitting information that is already contained in the databank as part of their submission of clinical trial results information and that such information has been updated as specified in § 11.64(c) and is to be included as clinical trial results information. Once this affirmation is made, the information listed in proposed § 11.48(a)(6) that had been previously submitted to the data bank, would automatically populate the results information data fields and be posted when results information is posted. This proposal would help us ensure that the clinical trial results information necessary ''to enhance patient access to and understanding of the results of clinical trials,'' consistent with section 402(j)(3)(D)(i) of the PHS Act is available to the public.

6. Submission of Non-Technical and Technical Summaries of Trial Results

Section 402(j)(3)(D)(iii)(I) of the PHS Act specifies that the regulations shall require ''[a] summary of the clinical trial and its results that is written in non-technical, understandable language for patients, if the Secretary determines that such types of summary can be included without being misleading or promotional.'' Section 402(j)(3)(D)(iii)(II) of the PHS Act specifies that the regulations shall require ''a summary of the clinical trial and its results that is technical in nature, if the Secretary determines that such types of summary can be included without being misleading or promotional.

We interpret the provisions in sections 402(j)(3)(D)(iii)(I) and (II) of the PHS Act to mean that the proposed regulations are to require the submission of non-technical and technical narrative summaries if such summaries can be produced in such a way that they will not be misleading or promotional to potential users of the data bank. We believe it is necessary to demonstrate that narrative summaries of applicable clinical trials can be consistently produced in a way that will not be misleading or promotional.

If non-technical or technical narrative summaries can be consistently produced without being misleading or promotional, patients, members of the general public, clinicians and researchers might benefit from brief, well-written, accurate, and objective summaries of the results of individual clinical trials. Such summaries might assist the public, clinicians, and researchers in understanding salient information about the characteristics of the participants in a specific applicable clinical trial and the benefits and harms experienced by those participants in that clinical trial. In fact, some users of ClinicalTrials.gov might find narrative summaries easier to understand than the summary results tables. Although summarized evidence from multiple clinical trials and observational studies, when available, would provide a more complete overall picture of a clinical trial's results, summaries of individual trials that are accurate and objective could also be useful, particularly for clinical trials that present the first evidence of benefits and harms for specific products or population groups, based on the experience of participants in that clinical trial.

Another consideration is the optimum format for narrative, non-technical summaries. For example, two existing widely-endorsed and used formats intended for reporting results of individual clinical trials for technical or expert audiences are the CONsolidated Standards for Reporting Trials (CONSORT) Statement [Ref. 31], a checklist of best practices for producing journal articles that report the results of clinical trials of any type of intervention; and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) topic E3—Structure and Content of Clinical Study Reports (ICH E3) [Ref. 23], a required format for summarizing results of individual clinical trials of drugs in submissions to FDA and to agencies that regulate the use of drugs in other countries. Both of these formats require narratives and data tables, including information that is already submitted to ClinicalTrials.gov to meet the registration and results submission requirements under section 402(j) of the PHS Act.

The CONSORT Statement specifically addresses various ways in which reports of clinical trial results can be misleading and how to avoid these pitfalls, generally by providing additional types of information, such as limitations in trial design, participant populations, etc. The CONSORT Statement strongly recommends ''that at a minimum, authors should discuss the results of their trial in the context of existing evidence. This discussion should be as systematic as possible and not limited to studies that support the results of the current trial. Ideally, we recommend a systematic review and an indication of the potential limitation of the discussion if this cannot be completed'' [Ref. 31]. The ICH E3 format does not specifically address the potential for misleading narratives, but it does emphasize the need to address many specific topics whose omission might lead to a misleading summary, e.g., appropriateness of measurements, statistical analysis plans, determination of sample size, protocol deviations. The ICH E3 guidance document also addresses the importance of context by stating that ''Clinical relevance and importance of the results should be also discussed in light of other existing data'' [Ref. 23].

Another question to be addressed is whether a single, brief summary of an individual clinical trial can provide sufficient background or context to avoid being potentially misleading to a clinician or patient interested in the clinical significance of the results. Individual trials can contain a large number of primary and secondary outcome measures (more than 120 in some submissions to ClinicalTrials.gov), which would make it extremely difficult to prepare succinct summaries without presenting selective information about the outcome measures or adverse events, a process that can introduce bias into the summary. On the other hand, all of the data required in results reporting would be available alongside the technical and non-technical summaries, providing all data on outcome measures. In addition, we rely on publication of clinical trials results through scientific journals so scientists are accustomed to analyzing and reporting often complex data from their clinical trials. ClinicalTrials.gov links to publications where available to provide the user with additional information.

In addition to reviewing the relevant literature, we consulted with the FDA Risk Communication Advisory Committee (meeting summary available at: *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/ucm116558.htm*) and considered public comments from the public meeting held in April 2009 [Ref. 1]. We agree with those who commented that further research on this complex issue is warranted. Accordingly, NIH plans to undertake an evaluation to assess the value to the public of such summaries and whether they can be provided in a manner that is objective and not misleading. We are therefore deferring the decision about whether or not to require the submission of narrative summaries. We invite further public comment on methods that we might employ to help answer this question so that we can explore this issue more thoroughly before making a final determination.

Consistent with section 402(j)(3)(A)(ii)(II), NIH will continue to provide links, where possible, from individual clinical trials listed in ClinicalTrials.gov to related peer-reviewed literature and other authoritative information related to the intervention(s) studied or the disease or condition addressed. To avoid potential confusion, such links are indicated to have been added by the Agency and not by the responsible party.

7. Submission of the Full Protocol

Section 402(j)(3)(D)(iii)(III) of the PHS Act provides that the regulations shall require submission of ''[t]he full protocol or such information on the protocol for the trial as may be necessary to help to evaluate the results of the trial.'' This requirement could be satisfied in any of several ways: (1) Requiring submission of additional structured data elements derived from, or describing, the protocol; (2) requiring submission of portions of the final protocol or other narrative information about the conduct of the study that is associated with the protocol (e.g., a statistical analysis plan, if not part of the protocol); or (3) requiring submission of the full protocol at the time of results submission, meaning the final version of the protocol, including all protocol amendments, in a format such as PDF.

Evaluating the results of a clinical trial involves the careful study and appraisal of the clinical trial methodology, so that results can be interpreted and their significance assessed. It can require detailed information about the conduct of a clinical trial, including the methods of participant selection, randomization, and assignment to arms; methods of collecting baseline and clinical trial data; specific information about the interventions used in the clinical trial (e.g., other elements of care that were provided in addition to the specified interventions studied in the clinical trial); and assessment of adverse events. It can also require information on the statistical techniques used to analyze collected results information.

We received comments on submission of protocols at the public meeting in April 2009 [Ref. 1]. At that time, commenters did not know what other registration and results information would be proposed in this NPRM for submission to ClinicalTrials.gov and could not take those requirements into account in their comments. Most comments addressed the question of whether or not to require submission of the full protocol and did not consider other approaches to meeting the statutory requirement in section 402(j)(3)(D)(iii)(III) of the PHS Act. Given the proposals for submission of additional registration and results information detailed in section IV of this preamble, we are not proposing to require submission of the full protocol or other ''information on the protocol.''

We invite public comment on whether the registration and results information that is proposed for submission in this NPRM is sufficient to meet the statutory requirement in section 402(j)(3)(D)(iii)(III) of the PHS Act to provide ''information on the protocol'' as may be necessary to help evaluate the results of the clinical trial or whether submission of additional information, including submission of the full protocol, should be required. Comments should address the relative benefits and burdens of preparing and submitting any additional information and should indicate how such information will help evaluate the results of the clinical trial. We will consider such input in formulating the final rule.

8. Increasing the Time Period for Submitting Results Information

Section 402(j)(3)(D)(iv)(I) of the PHS Act requires that the Secretary determine, by regulation, whether the deadline for submission of clinical trial results information of 1 year after the completion date of the applicable clinical trial—the deadline established in section 402(j)(3)(E)(i) of the PHS Act, which does not apply when a certification for delay is submitted or a request for extension is granted—should be increased from 1 year to a period not to exceed 18 months. The public comments on this matter helped inform our view [Ref. 1]. We believe there is value in making results information for primary outcome measures available within 1 year of the completion date. We therefore have decided not to propose lengthening the deadline for submitting results information, but to propose specific mechanisms for accommodating extended data collection for secondary outcomes to avoiding the premature unblinding of trials.

Proposed § 11.44(a)(1) provides that clinical trial results must be submitted no later than 1 year after the completion date of the clinical trial, unless a certification for delay is submitted or a request for extension is granted. In accordance with the statutory definition in section 402(j)(1)(A)(v) of the PHS Act, the term ''[c]ompletion date'' is defined in proposed § 11.10—for a clinical trial—to mean ''the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated. In the case of clinical trials with more than one primary outcome measure with different completion dates, this term refers to the date upon which data collection is completed for all of the primary outcomes.''

We interpret the phrase ''primary outcome'' to be synonymous with the phrase ''primary outcome measure.'' In the event that clinical trial results data for all pre-specified secondary outcome measures have not been collected by the completion date, proposed § 11.44(a)(2) provides a process for submitting ''partial results'' to the data bank. In particular, the responsible party will remain responsible for submitting results information for each remaining secondary outcome measure until the responsible party has submitted results data, including associated adverse event data, for all pre-specified outcome measures. Such results information must be submitted no later than 1 year after the date on which the final subject was examined or received an intervention for purposes of final data collection for the secondary outcome measure at issue. In cases where results submission under our proposed schedule would necessitate unblinding a trial, and doing so would affect a pre-specified secondary outcome measure, responsible parties should submit a request for an extension of the deadline for good cause, which must contain the elements outlined in proposed § 11.44(e). As discussed in greater detail in section IV.C.3(d) of this preamble, we believe that the need to preserve the scientific integrity of an applicable clinical trial for which data collection is ongoing would, in general, constitute good cause for an extension.

Based on our experience with approximately 1,200 data providers who have submitted results data to ClinicalTrials.gov, 1 year after the completion date of a clinical trial appears to be a reasonable amount of time for electronic data submission. We are aware of other results submission requirements (e.g., in Germany and the European Union) that define completion date as last patient, last visit (LPLV), instead of the final data collection for primary outcome as defined in section 402(j)(1)(A)(v) of the PHS Act. The European Union proposal would require results to be submitted within 6 months of the LPLV date of completion [Ref. 28].

To inform our proposal, we reviewed in the summer of 2009 a set of 230 randomly selected clinical trials registered in ClinicalTrials.gov. We found that about 80 percent of the clinical trials listed a single time frame for all pre-specified primary and secondary outcome measures. In other words, completion date as defined in section 402(j)(1)(A)(v) of the PHS Act and LPLV are identical for most of the clinical trials.

We recognize that many factors, such as rate of participant enrollment, may contribute to when final data are collected for the primary outcome measure. Thus, we propose that the responsible party: (1) As specified in § 11.10(b)(17) provide a reasonable estimate of the completion date upon registering the clinical trial (the Agency interprets ''estimated completion date'' as used in section 402(j)(3)(E)(i)(I) of the PHS Act to be synonymous with ''expected completion date'' as used in section 402(j)(2)(A)(ii)(I)(jj) of the PHS Act); and (2) update the information to indicate the actual completion date in accordance with the time frame established in § 11.64(b)(1)(viii). We note, if the estimated completion date of a clinical trial changes before or during the clinical trial, the responsible party would be required to update estimated completion date information consistent with § 11.64.

Updating the estimated completion date promptly to reflect the actual completion date is important because, as proposed, responsible parties would need to submit clinical trial results information not later than 1 year after the actual completion date (unless they submit a certification for delayed results submission or a request for a good-cause extension is granted). Hence, as described in proposed § 11.64, we propose to require that responsible parties update the completion date in ClinicalTrials.gov not later than 30 calendar days after a change. As with other data elements at ClinicalTrials.gov, all changes to posted information are tracked publicly at the ClinicalTrials.gov archive.

9. Retroactive Submission of Additional Results Information

Section 402(j)(3)(D)(iv)(II) of the PHS Act provides that the Secretary shall, by regulation, determine ''whether the clinical trial information described in [section 402(j)(3)(D)(iii) of the PHS Act] should be required to be submitted for an applicable clinical trial for which the clinical trial information described in [section 402(j)(3)(C) of the PHS Act] is submitted to the registry and results data bank before the effective date of the regulations.'' The clinical trial information described in section 402(j)(3)(D)(iii) of the PHS Act refers to: (1) technical and non-technical narrative summaries of the clinical trial, (2) the protocol or other information on the protocol to help evaluate the results of the trial, and (3) other categories of information as determined to be appropriate by the Secretary.

As explained in sections III.C.6 and III.C.7 of this preamble, we do not propose in this rule a requirement for the submission of technical or nontechnical narrative summaries or for the submission of the full protocol (although we invite public comment on both topics). We propose to require submission of ''other categories of information'' in two situations: When a responsible party submits results for applicable clinical trial of a device that has not been cleared or approved (see section IV.C.4.f of this preamble); and when a responsible party submits results information voluntarily under section 402(j)(4)(A) of the PHS Act. Neither of these situations would apply to clinical trials for which results information is submitted prior to the effective date of the rule because responsible parties would not be required prior to the effective date of the rule to submit results of applicable clinical trials of devices that are not approved or cleared; nor would they be subject to the voluntary submissions provisions in section 402(j)(4)(A) of the PHS Act. Therefore, we do not propose to require the submission of clinical trial information described in section 402(j)(3)(D)(iii) of the PHS Act for an applicable clinical trial for which the clinical trial results information is submitted to ClinicalTrials.gov before the effective date of the regulations. As described in section III.D of this preamble on Effective Date, we do, however, propose to require the responsible party for an applicable clinical trial that reaches its completion date prior to the effective date of the final rule to submit all of the results information specified in proposed § 11.48 if the responsible party has not submitted results information prior to the effective date of the rule. Requiring the submission of this information would improve the uniformity and consistency of information available in the data bank for applicable clinical trials.

10. Standard Data Formats

Section 402(j)(3)(D)(v)(I) of the PHS Act provides that regulations regarding the submission of expanded results information shall also establish ''a standard format for the submission of clinical trial information under [section 402(j)(3)(D)(v)(I) of the PHS Act] to the registry and results data bank.'' Proposed § 11.48 of this proposed rule implements standard data formats for results information, including adverse event information, taking into consideration comments made at the public meeting [Ref. 1].

As discussed in sections II.B and III.C.12 of this preamble, NLM is adopting a tabular, structured data entry

system to promote objective reporting, optimize data display, permit effective searching of ClinicalTrials.gov, and facilitate cross-trial comparisons. To the extent possible, our proposal for submitting adverse event information is consistent with ICH–E3 formats (see *http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073113.pdf*) and Body Organ System Class for grouping adverse events by organ system, as required by the statutory default provisions in section 402(j)(3)(I)(iii) of the PHS Act. We have developed a mechanism for uploading results data in an automated electronic fashion using eXtensible Markup Language (XML) files. We do not believe that uploads of data tables in other formats will allow for the comparability and consistency desired across trials and do not include such a mechanism in our proposal.

11. Additional Information to Improve Patient Understanding of Submitted Information

Section 402(j)(3)(D)(v)(II) of the PHS Act requires that the regulations establish ''additional information on clinical trials and results that is written in nontechnical, understandable language for patients[.]'' We interpret this provision to mean, in part, that the regulations must specify additional expanded results information that responsible parties would be required to submit to ClinicalTrials.gov to assist patients in understanding and interpreting other submitted clinical trial information.

As discussed elsewhere in this preamble (see sections III.C.2 and III.C.15) and in several sections of this proposed rule, we propose additional data elements or types of information that responsible parties must submit to enhance the interpretability of submitted information related to registration and results, including adverse events. In developing the proposed regulation, we took into account numerous suggestions that were made at the public meeting about resources that could be included in the data bank to assist patients in understanding and interpreting information in the data bank [Ref. 1].

Although section 402(j)(3)(D)(v)(II) of the PHS Act does not require the Agency to develop and provide additional information in ClinicalTrials.gov to assist users in better understanding and interpreting the submitted clinical trial information, we have paid careful attention to comments about how the ClinicalTrials.gov Web site might be improved. ClinicalTrials.gov already contains site-level resources to assist patients and other users in obtaining and understanding information on clinical trials in the data bank, e.g., FAQs on understanding clinical trials, a glossary of clinical trial terms, and an introduction that describes the general purpose and content of the data bank and cautions that the information should be used in conjunction with advice from healthcare professionals. In addition, each clinical trial record contains links to definitions that explain to the public standard terms such as ''condition'' and ''intervention;'' and, where it exists, to information at select consumer health Web sites that is relevant to the clinical trial. Such information includes: resources related to the conditions being studied, from MedlinePlus (*http://www.nlm.nih.gov/medlineplus/*) and the Genetics Home Reference (*http://ghr.nlm.nih.gov/*); resources related to the intervention(s) being investigated, from the NLM Drug Information Portal (*http://druginfo.nlm.nih.gov/*) and FDA's Web site (*www.fda.gov*); and publications related to the clinical trial, including freely available abstracts if available, from PubMed (*http://www.ncbi.nlm.nih.gov/pubmed/*). As noted in section III.C.6 of this preamble, we intend to add links from clinical trial records to other sources of related, authoritative health information (e.g., information from government sources and/or peer reviewed publications). Such information will be labeled as being added by NLM.

12. Quality Control Procedures

Section 402(j)(3)(D)(v)(III) of the PHS Act provides that the regulations shall also establish procedures for quality control ''with respect to completeness and content of clinical trial information,'' including using representative samples, in order ''to help ensure that data elements are not false or misleading and are non-promotional[.]'' In developing such procedures, the Agency is to consider the experience gained through the pilot quality control project, described in section 402(j)(5)(C)(i) of the PHS Act. The pilot quality control project is ''to determine the optimal method of verification to help ensure that the clinical trial information submitted under . . . [section 402(j)(3)(C) of the PHS Act] is non-promotional and is not false or misleading in any particular . . .'' (See section 402(j)(5)(C)(i) of the PHS Act). Comments submitted to the docket and discussed at the public meeting also have been considered in developing the quality control procedures [Ref. 1].

We note that Section 801(d)(2) of FDAAA includes a Rule of Construction, which states that the ''submission of clinical trial information, *if submitted in compliance* with [section 402(j) of the PHS Act], that relates to the use of a drug or device not included in the official labeling of the approved drug or device shall not be construed by the Secretary of Health and Human Services or in any administrative or judicial proceeding, as evidence of a new intended use of the drug or device that is different from the intended use of the drug or device set forth in the official labeling of the drug or device.'' Public Law 110–85, section 801(d)(2) (emphasis added). Section 801(d)(2) further states that the availability of clinical trial information through the data bank, if submitted in compliance with such subsection, shall not be considered as labeling, adulteration, or misbranding of the drug or device under the FD&C Act.

Consistent with many of the comments we received, we have designed the ClinicalTrials.gov results submission system to encourage objective reporting. As discussed in section III.C.10 of this preamble, the tabular, structured data entry system developed for ClinicalTrials.gov promotes objective reporting, optimizes the data display and permits effective searching of the data bank. In addition, as discussed in section III.C.6 of this preamble we have not included a proposed requirement to submit non-technical and technical narrative summaries of the results of a clinical trial. We intend to study this issue further and are inviting additional public comment on it. At present, procedures for quality control relate to the review of structured data that would be required to be submitted to ClinicalTrials.gov under this proposed rule.

(a) Pilot Quality Control Project. As a preliminary step toward satisfying the required pilot quality control project under section 402(j)(5)(C)(i) of the PHS Act, we conducted a quality control study that consisted of two parts as follows: (1) review of the results of more than 4,500 clinical trials submitted under section 402(j)(3)(C) of the PHS Act after September 27, 2008; and (2) an initial validation study of the ClinicalTrials.gov results data bank, conducted under contract by researchers at the Oregon Health Science University [Ref. 32].

The first part of the quality control study led to the development of detailed quality review criteria [Ref. 33, 34].

Since the launch of the ClinicalTrials.gov results data bank, each submission of results information has been reviewed for apparent validity, meaningful entries, logical and internal consistency, and formatting. We have tried to ensure that submitted results information is objective and contains no comments about conclusions, clinical implications, or comparisons with other studies or other data. Table 1 lists common types of errors, deficiencies and inconsistencies with specific examples that were seen during this time period. Data submitters were notified of errors, deficiencies and/or inconsistencies found during this first part of the quality control study and asked to revise their submissions. During this period, clinical trial results information was not posted in ClinicalTrials.gov until the errors, deficiencies and/or inconsistencies identified by the quality review had been addressed by responsible parties. In some cases, corrected information was not provided until more than 30 days had passed from the initial submission.

To assist responsible parties in avoiding such errors, deficiencies and inconsistencies, we developed and continue to refine documentation explaining how to meet the quality review criteria; identified and compiled lists of frequent errors, deficiencies and inconsistencies in submitted results information; and provided system support to help responsible parties minimize such errors, deficiencies and inconsistencies. We also have provided intensive user support for responsible parties who are new to the online results submission process, whether through data entry using Web-based forms or automated uploading of data files. We have developed and posted draft educational materials, such as tips on improving results submissions and ways to avoid common errors, deficiencies and inconsistencies observed in submissions to date. All such documents are available at *http://prsinfo.clinicaltrials.gov/fdaaa.html.* We will continue to provide support to responsible parties and, based on these interactions, develop new or updated materials in order to facilitate and streamline preparation of results data for submission to ClinicalTrials.gov and to help ensure that the submissions meet the quality review criteria.

TABLE 1—SOME COMMON TYPES OF ERRORS, DEFICIENCIES AND INCONSISTENCIES IDENTIFIED IN RESULTS SUBMISSIONS

Data quality category	Description	Example	Explanation
Lack of apparent validity	Data not plausible based on information provided.	Outcome measure indicating a mean value of 263 hours per day of sleep.	Measure of mean hours per day can only have values in the range of 0–24. Value of ''263'' is not valid.
Incomplete Information	Information insufficient to convey intended meaning.	Outcome measure description states ''clinical evaluation of adverse events, laboratory parameters and imaging''; data reported as 100 and 96 participants, in each arm.	Data are uninformative. Unclear to what counts of 100 and 96 participants refer. Outcome measure description not sufficiently descriptive to understand specific outcome.
Incomplete information	Information insufficient to convey intended meaning.	Outcome measure assessed on a scale, which is not explained; data reported as mean values of 3.2 and 4.1 in the two arms.	Data are uninformative without an explanation of what the scale is assessing and the range and direction of scores (e.g., whether 3.2 is better or worse than 4.1 on a 5-point scale).
Internal inconsistency	Data not consistent with descriptive information.	Outcome measure title is ''time to disease progression;'' data reported as 42 & 21 participants, in each arm.	A time-to-event measure requires a unit of time such as days or months.
Internal inconsistency	Data in one section are not consistent with data in another section.	Baseline characteristics & participant flow entered as 2-armed study with a total of 400 participants; outcomes entered for 3 arms with 600 participants.	If there is a third group, then Baseline Characteristics and Participant Flow modules must reflect this or group descriptions in Outcomes should explain their origin.

These efforts have produced significant improvements in the quality of initial submissions of results information to ClinicalTrials.gov. Whereas in 2008 only 5 percent of submissions met the quality review criteria when first submitted, by 2012 approximately 36 percent of initial submissions met the quality review criteria. Improvements in the percentage of initial results submission that meet our quality review criteria may be a consequence of three factors: (1) greater familiarity among responsible parties and sponsors with the system and the associated rules, (2) better resource materials from ClinicalTrials.gov, and (3) growing awareness that the task of entering results requires involvement of personnel with a full understanding of the trial design and results. The number of responsible parties submitting data has increased each quarter.

The second part of the quality control study compared the consistency of posted results information for phase 3 or 4 clinical trials of drugs that were completed prior to January 1, 2009 and had submitted results by November 17, 2010 with results information published in peer reviewed journals and documents made publicly available on the FDA Web site, such as medical reviews. A publication was identified for only 32 percent of the 342 trials that were sampled, and in 82 percent of the publication-trial pairs at least one discrepancy was found between the data submitted to ClinicalTrials.gov and the data contained in the peer-reviewed journal article. Discrepancies occurred in almost all fields analyzed, including number of arms, primary and secondary outcome measures (the name of the measure as well as the actual data), total enrollment, and number of serious adverse events. In cases where the publication addresses a subset of the data in the trial, the apparent discrepancies could be correct reflections of the clinical trial results for the population covered [Ref.38].

The study results demonstrate that comparisons with publications cannot be used in real time to validate results submissions to ClinicalTrials.gov. For the great majority of clinical trials, no publications are available for comparison at the time results are submitted to the data bank. In addition, for clinical trials of products that have not been approved, licensed, or cleared, or for which a new indication is being

studied but has not yet been approved, licensed, or cleared, information about the clinical trial ordinarily is not available on FDA's Web site at the time results are submitted to ClinicalTrials.gov. Thus, we do not believe that comparisons with publications or FDA documents would provide a feasible or effective method of routinely screening submitted clinical trial records with results to help ensure that the clinical trial information is non-promotional and not false or misleading in any particular.

As required by section 402(j)(5)(C)(i), we plan to continue conducting the pilot quality control project in coordination with the Commissioner of Food and Drugs until the effective date of this regulation to determine the optimal method of verification to help ensure that the clinical trial information submitted under section 402(j)(3)(C) of the PHS Act is non-promotional and is not false or misleading in any particular. In addition, we will continue to use comparisons with random samples of publications or public FDA documents to identify problems and improve our procedures. In addition, if we become aware of a publication or FDA document that appears to contain information that is inconsistent with a submitted clinical trial record, we will consult with FDA on the appropriate next steps.

(b) Proposed Quality Control Procedures. Based on the public comments we received, experience with the preliminary steps of the pilot quality control project, and consistent with current practice, we intend to continue a form of quality control at the time of clinical trial registration or submission of clinical trial results information that is similar to the procedures we have been using for the past several years. The quality control process will not affect the statutory deadlines for submitting or publicly posting submitted clinical trial information.

Our quality control process cannot determine the veracity of the data submitted, and all entries in ClinicalTrials.gov will carry a disclaimer to that effect. Our quality control process is intended to help ensure that clinical trial information posted on ClinicalTrials.gov has face validity and is free from obvious errors. The identification of two or more data elements within a clinical trial record that are internally inconsistent is an effective method of identifying errors since, by logic, both pieces of data cannot be correct. By providing responsible parties with information as to which elements of submitted clinical trial information do not meet specified quality review criteria, we can better facilitate access by the public to information that is not obviously incomplete, incorrect, or inconsistent.

Overall, our proposed quality control process for submission of clinical trial registration information or clinical trials results information will consist of two sequential components as follows: (1) an automated system-based check, followed by (2) a detailed, manual review. In the first component, the ClinicalTrials.gov system would alert responsible parties to machine-detectable errors in the data entered (e.g., certain types of missing information that is required, certain types of impossible values, certain types of internally inconsistent data). The number of automated checks the system performs has increased over time as we have gained experience with the types of errors that occur and devised additional automated rules for detection. We will continue to refine the automated checks in order to assist submitters in detecting and minimizing errors, deficiencies, and inconsistencies in the information they are submitting.

Once clinical trial information has passed the automated checks and been submitted, we would begin the second component of quality control: the detailed, manual review. We would review all data submissions that pass the automated system checks in order to identify, based on detailed quality review criteria, additional apparent errors, deficiencies, or inconsistencies that are not detected by the automated checks. If problems are identified in the detailed, manual review, we would send an electronic notification to the responsible party, indicating that the submission contains apparent errors, deficiencies and/or inconsistencies listing the errors, deficiencies and/or inconsistencies found, and requesting correction. Consistent with the proposal in § 11.66 regarding correction of clinical trial information, responsible parties would be required to correct the errors, deficiencies and/or inconsistencies not later than 15 calendar days after being informed of them by the Agency or otherwise becoming aware of them (e.g., if they discover the errors, inconsistencies, and/or deficiencies themselves), whichever is later. (See the discussion of the corrections provision in section IV.D.4 of this preamble).

We expect to complete the quality control process and to receive submissions of corrected clinical trial information prior to the deadlines for posting such information publicly, as established by sections 402(j)(2)(D) and 402(j)(2)(G) of the PHS Act. We recognize that in some situations, the quality review process may not be completed prior to the statutory posting deadlines, and we will have to post submitted information that has not been corrected. Clinical trial information posted without having completed the quality control review and any necessary correction by the responsible party will include a statement indicating that it has not completed the quality control process. Users searching ClinicalTrials.gov will be able to elect to include or exclude clinical trial registrations or clinical trial results information that have not yet completed the quality control process proposed in this NPRM. When revised information correcting the noted errors has been submitted and the revised information has passed the quality control process, the statement that the clinical trial record has not completed the quality control process would be removed from the posted record. However, the information that was initially posted prior to completion of the quality control review would appear in the archived history for that clinical trial entry, and the archived version would indicate that it had been posted with a notice. The electronic notification sent to the responsible party would inform responsible parties of these facts.

We believe additional precautions must be taken with clinical trial registration information that has not completed quality review. Clinical trial registration information may be used by patients and healthcare providers who are considering enrollment in a clinical trial. Although we will post information submitted when clinical trials are registered consistent with the time frames in section 402(j)(2)(D) of the PHS Act and with the statement described above, we will not assign an NCT number until information submitted has completed our quality control process. Thus, if the quality control process and any necessary data correction by the responsible party have not been completed within calendar 30 days after an applicable drug clinical trial has been registered, the information submitted will be posted without an NCT number. This approach is consistent with the practice that has been in effect since ClinicalTrials.gov was launched in 2000. This approach would ensure that the existence of an NCT number for a specific clinical trial remains an indicator both that a publicly posted clinical trial has been registered and that the registration of the clinical trial has gone through the proposed two-stage quality control process. Use of NCT numbers is

required in certain submissions to FDA and in reports to NIH and other HHS agencies from relevant grantees and contractors as evidence that clinical trials have been publicly registered, as required by section 402(j) of the PHS Act, and by other stakeholders, including journal editors, as evidence of public disclosure of certain protocol information. In our experience in operating the registry component of ClinicalTrials.gov, we have found that clinical trial registration information can be reviewed quickly and that responsible parties can submit corrected information in a matter of days.

Other elements of quality control are described in proposed § 11.66 and section IV.D.4 of this preamble. We recognize that clinical trial data elements that are submitted as free-text could be phrased in a manner that might be considered promotional or misleading. We solicit comment on ways in which the descriptions of the data elements in the proposed codified could be improved to help ensure that submitted clinical trial information is not promotional or misleading. We also seek comment on standards we could use for determining when clinical trial information should be considered to be promotional. Finally, we solicit comment regarding how the pilot quality control project may help ensure that the clinical trial information submitted under paragraph (j)(3)(C) is non-promotional and not false or misleading under paragraph (j)(5)(D).

We note that compliance with our quality control process, including the requirements set forth in § 11.66, does not necessarily constitute a legal defense to enforcement pursuant to section 301(jj) of the FD&C Act (21 U.S.C. 331) and 303(f) of the FD&C Act (21 U.S.C. 333(f)).

13. Updating Submitted Clinical Trial Information

Section 402(j)(3)(D)(v)(IV) of the PHS Act provides that the regulations shall also establish ''the appropriate timing and requirements for updates of clinical trial information, and whether and, if so, how such updates should be tracked.'' Section 402(j)(4)(C) of the PHS Act, separately requires responsible parties to submit updates of clinical trial registration information to ClinicalTrials.gov not less than once every 12 months (except for certain specified data elements for which more rapid updates are required), and the Director to post such updates publicly in the data bank. With regard to the requirement in section 402(j)(3)(D)(v)(IV) of the PHS Act to establish, by regulation, ''the appropriate timing and requirements for updates of clinical trial information . . .,'' we interpret the term ''clinical trial information'' to mean both information submitted when a clinical trial is registered and clinical trial results information, consistent with the definition of ''clinical trial information'' in section 402(j)(1)(A)(iv) of the PHS Act. In addition, our proposed requirements for updates apply to adverse event information because adverse event information is deemed to be clinical trial results information under section 402(j)(3)(I)(v) of the PHS Act. Our proposals take into consideration comments made at the public meeting [Ref. 1].

Proposed § 11.64(a)(1) provides that, in general, updates of clinical trial information must be provided every 12 months, unless there are no changes during the previous 12 months. Proposed § 11.64(a)(2) specifies that a responsible party must submit updates until the final clinical trial results information has been submitted for all primary and secondary outcome measures and all adverse events collected in accordance with the protocol. After all such results information has been submitted, a responsible party's obligation to update the record would end unless and until the responsible party becomes aware of errors in the submitted clinical trial information. In that case, the responsible party would need to submit corrected information as specified in proposed § 11.66.

Proposed § 11.64(b) identifies several data elements that must be updated not later than 30 days after a change occurs (e.g., Overall Recruitment Status and Availability of Expanded Access), requires updates to U.S. FDA Approval, Licensure, or Clearance Status not later than 15 calendar days after the change occurred, and specifies that if a protocol is amended in such a manner that changes are communicated to participants in the clinical trial, updates to relevant clinical trial information must be submitted no later than 30 calendar days after the protocol amendment is approved by the human subjects protection review board. A responsible party would also be required to update the Record Verification Date any time the responsible party reviews the complete clinical trial record for accuracy, even if no other updates are submitted at that time. The above exceptions to the 12-month period for updates are considered important for patients using the data bank to search for clinical trials for which they might qualify and for the Agency in administering other provisions of section 402(j) of the PHS Act. In addition, proposed § 11.64(c) would require a responsible party to update, as necessary, any previously submitted clinical trial information at the time results information is submitted to ClinicalTrials.gov (the responsible party would then be required to update the Record Verification Date data element). Doing so will improve the accuracy of information that is used by ClinicalTrials.gov to automatically prepopulate some elements of results information. Further discussion of these update requirements appears in the description of proposed § 11.64 in section IV of this preamble.

As set forth in proposed § 11.64(d)(2), all prior clinical trial information, including past updates of posted submissions, are tracked in the ClinicalTrials.gov archive, in which the full history of changes to clinical trial information for any clinical trial is accessible to the public. Note that, as discussed in section III.C.13 of this preamble, the time frames for updating registration and results information do not apply to corrections of errors, corrections of falsified data, and other corrections of clinical trial information, which should be made in accordance with the time frames proposed in § 11.66. (See section 402(j)(5)(D)(i) of the PHS Act.)

14. Statement To Accompany Certain Trials and Other Issues Related to Voluntary Submissions

Section 402(j)(3)(D)(v)(V) of the PHS Act provides that the regulations shall also establish ''a statement to accompany the entry for an applicable clinical trial when the primary and secondary outcome measures for such clinical trial are submitted under paragraph (4)(A) [voluntary submissions] after the date specified for the submission of such information in paragraph (2)(C)[.]'' Some applicable clinical trials are not subject to mandatory registration or submission of results information because they were not initiated after, or ongoing as of, the dates established in section 402(j)(2)(C) of the PHS Act (i.e., 90 days after the date of enactment of FDAAA). They would be considered ''submitted under paragraph (4)(A)'' if the responsible party submits the information voluntarily to ClinicalTrials.gov or if the responsible party is required to submit the information under section 402(j)(4)(A) of the PHS Act because the applicable clinical trial is included in a marketing application or premarket notification submitted to FDA. Submitted information might consist of

registration information and/or results information. We interpret section 402(j)(3)(D)(v)(V) of the PHS Act to require a statement to be posted with the clinical trial registration and/or the results information for such applicable clinical trials because primary and secondary outcome measures are required at the time of both registration and submission of results information. See 402(j)(2)(A)(ii)(ll) and (3)(C)(ii) of the PHS Act.

We note that for applicable clinical trials subject to section 402(j)(4)(A) of the PHS Act, it would be permissible for information about the primary and secondary outcome measures to be submitted after the deadline established for clinical trial registration under section 402(j)(2)(C) of the PHS Act. We interpret section 402(j)(3)(D)(v)(V) of the PHS Act to require a statement that clarifies that the submission was not subject to the deadlines imposed by section 402(j) of the PHS Act for clinical trial registration and submission of results information. Such a statement would be valuable in demonstrating to users of ClinicalTrials.gov that the submitted information is not out-of-compliance with the statutory deadlines for submitting information about the primary and secondary outcomes. Some commenters recommended specific language for the statement to accompany these voluntary submissions (Ref. 1).

We propose in § 11.60(b) that the following statement accompany each applicable clinical trial for which clinical trial information is submitted voluntarily to ClinicalTrials.gov under section 402(j)(4)(A) of the PHS Act or proposed § 11.60(a): ''Clinical trial information for this applicable clinical trial was submitted under section 402(j)(4)(A) of the Public Health Service Act and 42 CFR 11.60 and is not subject to the deadlines established by sections 402(j)(2) and (3) of the Public Health Service Act or 42 CFR 11.24 and 11.44.'' Proposed § 11.60 provides that a responsible party may voluntarily submit complete clinical trial information for trials of FDA-regulated drugs or devices that are not applicable clinical trials, such as phase 1 trials, but only if certain conditions are met. If a responsible party registers or submits clinical trial results information voluntarily for such a clinical trial, section 402(j)(4)(A) of the PHS Act requires that such information be complete, and that clinical trial information be submitted with respect to certain ''triggered'' applicable clinical trials. These requirements are discussed further in section IV.D.1 of this preamble.

15. Adverse Event Information

Section 402(j)(3)(I)(i) of the PHS Act requires the Secretary, by regulation, to ''determine the best method for including in the registry and results data bank appropriate results information on serious adverse and frequent adverse events for applicable clinical trials . . . in a manner and form that is useful and not misleading to patients, physicians, and scientists.'' Such regulations are to be issued not later than 18 months after the date of enactment of FDAAA (i.e., by March 27, 2009). Section 402(j)(3)(I)(ii) of the PHS Act specifies that if such regulations are not issued by the date that is 24 months after the date of the enactment of FDAAA (i.e., by September 27, 2009), a set of default provisions in sections 402(j)(3)(I)(iii)(I) and (II) of the PHS Act (referred to hereinafter as ''the statutory default provisions'') take effect. The statutory default provisions require submission of two tables of information, as follows: (1) ''A table of anticipated and unanticipated serious adverse events grouped by organ system, with number and frequency of such event in each arm of the clinical trial'' (section 402(j)(3)(I)(iii)(I) of the PHS Act), referred to hereinafter as the ''serious adverse events table''; and (2) ''A table of anticipated and unanticipated adverse events that are not included in the [serious adverse events] table . . . that exceed a frequency of 5 percent within any arm of the clinical trial, grouped by organ system, with number and frequency of such event in each arm of the clinical trial'' (section 402(j)(3)(I)(iii)(II) of the PHS Act). In this proposed rule and in ClinicalTrials.gov, we refer to adverse events that do not fit the definition of a serious adverse event as ''other adverse events,'' and we refer to the adverse event table in (2) as the ''other adverse events table.''

The statutory default provisions set forth in sections 402(j)(3)(I)(iii)(I) and (II) of the PHS Act became mandatory as of September 27, 2009. For a year prior to this date, responsible parties were able to submit adverse event data voluntarily and adjust the threshold for other adverse events to the level of their choice. Such an approach allowed us to test whether frequency thresholds other than 5 percent were better suited to the submission of information about other adverse events and might constitute the ''best method'' for submitting information about other adverse events. Responsible parties were also able to submit comments on the way ClinicalTrials.gov collected adverse event information so that we could improve the design and implementation of the system. [*See:* Docket NIH–2009–0002]

Our proposal for submitting adverse event information in § 11.48(a)(4) is based on the statutory default provisions in sections 402(j)(3)(I)(iii)(I) and (II) of the PHS Act, with some modifications. We believe that the Secretary has authority to modify the statutory default provisions by regulation under section 402(j)(3)(D)(v)(VI) of the PHS Act, which specifies that the regulations shall establish ''additions or modifications to the manner of reporting of the data elements established under [section 402(j)(3)(C) of the PHS Act].'' Section 402(j)(3)(I)(v) of the PHS Act deems adverse event information to be ''clinical trial information included in [the] data bank pursuant to . . . [section 402(j)(3)(C) of the PHS Act],'' and we believe that this clinical trial information is coextensive with the ''data elements established under . . . [section 402(j)(3)(C) of the PHS Act][,]'' referred to in section 402(j)(3)(D)(v)(VI) of the PHS Act. Therefore, we conclude that the Secretary has authority, under section 402(j)(3)(D)(v)(VI) of the PHS Act, to modify the statutory default provisions for submission of adverse event information via regulation, provided that such modifications represent ''additions or modifications to the manner of reporting [adverse event information] . . .''

We propose to maintain the requirement under the statutory default provisions in sections 402(j)(3)(I)(iii)(I) and (II) of the PHS Act to submit two tables of information summarizing anticipated and unanticipated adverse events that were collected in accordance with the protocol, i.e., one table for all serious adverse events and one table for other adverse events that exceed a frequency of 5 percent within any arm of the trial. We would continue to allow the submission of other adverse events with a frequency of less than 5 percent on a voluntary basis, as many data submitters have continued to do. Consistent with the statutory default provisions, our proposal would require submission of information on all such adverse events, not only those that are unanticipated or considered attributable to interventions studied in the clinical trial, to the extent that the collection of these data was specified in the protocol for the trial. By including information on adverse events, regardless of whether or not they were considered anticipated or attributed to the intervention(s) studied in the clinical trial, ClinicalTrials.gov would provide an

objective summary of the adverse events that were collected during the trial.

We do not intend for our proposal to cause an investigator to collect adverse event information of a type or in a way that is not specified in the protocol. For clinical trials for which the protocol specifies collection of only a limited set of adverse events (e.g. unanticipated adverse reactions), we would require the responsible party to submit to ClinicalTrials.gov a summary of the information that was collected during the clinical trial about serious adverse events and other adverse events that exceed a frequency of 5 percent within any arm of the trial. In addition, as specified in proposed § 11.48(a)(4)(ii)(H), we would require the responsible party to describe how the types of adverse events collected in the clinical trial differ from the types of adverse events and serious adverse events defined in proposed § 11.10. We believe this proposal would provide responsible parties with a convenient means of submitting required adverse event information without causing them to collect and submit information that is not specified in the protocol. It would also permit users of ClinicalTrials.gov to understand how submitted adverse event information differs in scope and kind from the adverse event information defined in this part.

Implementing the statutory default provisions for adverse event information entails an interpretation of the requirement to submit information describing the ''number and frequency'' of adverse events. Sections 402(j)(3)(I)(iii)(II) and (III) of the PHS Act do not specify whether the number and frequency of adverse events refer to the number of participants who experience an adverse event and the frequency relative to the number of participants assessed for that adverse event (i.e., the number of participants who were ''at risk'' for experiencing that adverse event) or to the absolute number of adverse events or occurrences, independent of the number of participants involved. When an adverse event occurs only once in a participant, the two methods of summarizing adverse event data are equivalent (i.e., the number of participants experiencing an adverse event is equal to the number of events that occurred). However, when an adverse event occurs multiple times in a single participant, information about the number of adverse events without information about the number of affected participants could be confusing. For example, if the submitted information indicates that 20 headaches occurred in an arm with 100 participants, it would be unclear how many participants experienced headaches: the number could range from as many as 20 participants with one headache each to as few as one participant with 20 headaches.

We interpret the statutory default provisions to require submission of information about the number of participants who experienced an adverse ''event'' and the total number of participants at risk for the adverse event. This interpretation is consistent with existing conventions for summarizing adverse event information (e.g., CONSORT Statement on Harms) and supports the important objective of summary results submission, which is to allow users to compare the number of participants who may have benefited from a particular intervention with the number who experienced adverse events during a trial. Consistent with requirements in effect at ClinicalTrials.gov since September 2009, we propose that responsible parties submit both the number of participants who experienced an adverse event and the total number of participants at risk for the adverse event. ClinicalTrials.gov provides features to simplify submission of the number at risk (e.g., when the number at risk is the same for all adverse events submitted) and would use this information in combination with the number of participants affected to compute the frequency automatically.

We also believe there is value in making information available about the number of adverse events. Since September 2009, responsible parties have had the option of voluntarily submitting the total number of occurrences of each adverse event in addition to the number of participants affected. Many responsible parties have submitted this information voluntarily; nearly half of the results submitted in 2012 for clinical trials that appear to meet the definition of applicable clinical trials included the total number of occurrences for adverse events. We will continue to provide a mechanism for responsible parties to voluntarily provide event level information for adverse events.

We considered, but do not propose, requirements for responsible parties to provide the total number of occurrences of each serious adverse event and the number of such occurrences considered, as of a specific date, to be attributable to the intervention(s) under study. Participants in many clinical trials have serious conditions that cause adverse events; they are also subject to the accidents and other unpredictable health events that affect the general population. During the course of a clinical trial, participants may die or suffer other serious adverse events due to causes that are unrelated to the interventions they are receiving as part of the clinical trial. Evaluating whether a specific adverse event is likely to have been caused by an intervention studied in the clinical trial can be valuable while the clinical trial is ongoing and data are still being collected because it can lead to modifications in the clinical trial to better protect the human subjects. The value of attribution at the level of an individual adverse event is less certain after a clinical trial has completed and all clinical trial data have been collected. The determination of attribution is, by its nature, subjective, influenced by various biases, and can change over time within a given clinical trial. The ''gold standard'' for assessing possible causal relationships between an adverse event (or a series of adverse events) and an intervention after completion of a clinical trial is an empirical comparison of the adverse events that occurred in different arms of the clinical trial. Because adverse event information would be submitted to ClinicalTrials.gov after completion of a clinical trial (as long as three years after the completion date if the responsible party submits a certification for delayed results submission), we do not propose a requirement for including attribution information. We invite public comment on any aspect of this issue, as well as information about current practices for attribution of serious adverse events that might help us to refine proposed requirements for submission of adverse event information.

To further assist users in understanding and interpreting submitted adverse event information, we propose to require the submission of additional information, based on our experience in operating ClinicalTrials.gov to-date. Some of this information is already collected on a voluntary basis in ClinicalTrials.gov, and some has been required since September 2009, but one data element is new.

We propose to continue to require responsible parties to submit information about adverse events by organ class for each arm and for each table (serious adverse events and other adverse events), as required by the statutory default provisions in section 402(j)(3)(I)(iii)(I) and (II) of the PHS Act. We propose to require responsible parties to use the organ system classes specified in the Medical Dictionary for Regulatory Affairs (MedDRA) (*http://www.meddramsso.com/*) to classify the specific adverse event terms (e.g., nausea) by organ system. Our

experience with voluntary and mandatory adverse events submission since September 2008 indicates that responsible parties are able to use these classes effectively and that a single set of organ system classes provides a consistent way to display information about adverse events between tables for a trial and across trials.

We also propose to require responsible parties to submit the total number of participants affected by an adverse event at the organ system level. This information would be required for each arm of the clinical trial and for each adverse event table (serious adverse events and other adverse events). Section 402(j)(3)(I)(iii) of the PHS Act requires the listing of adverse events by organ system. We believe that one purpose of this provision is to enable comparisons across arms even when there are variations in the level of specificity or granularity of the data submitted. Unless the total number of participants with adverse events is provided at the level of the organ system, the serious adverse event and other adverse event tables will not be able to support such comparisons. For example, if one trial lists 5 participants with ''rash'' under the ''Skin and subcutaneous tissue disorders'' organ system category and another lists 2 participants for each of three specific types of rashes under the same category, it is not possible to know which trial had more participants with adverse events affecting the skin, because certain participants in the second trial could have suffered more than one type of rash. Thus, in order to obtain an important benefit of listing adverse events by organ system, we believe that it is necessary to require responsible parties to submit the total number of participants affected by any adverse event within each organ system for which adverse event data were collected. For organ systems that do not have a submitted adverse event, ClinicalTrials.gov will automatically assume that the total number of participants affected by that organ system is 0 (zero) for serious adverse events, and less than the 5 percent threshold for other adverse events, which will reduce the burden of this proposed requirement.

We also propose to continue to require responsible parties to submit information about the total number of participants affected by any adverse event for each arm in each table. As described earlier in this section, it is our view that this information permits better interpretation of the adverse event data by clearly presenting how many participants were affected by any adverse event in a given arm of the clinical trial.

We also considered, but do not propose to require submission of several other types of information describing the collection of adverse events in a clinical trial. Responsible parties are currently able to submit some of this information voluntarily. We invite public comment on the potential benefit and burden of requiring that the following types of information be submitted to ClinicalTrials.gov. We will consider comments in preparing the final rule.

Time frame: Time frame information would specify when during the clinical trial adverse event information was collected. Information on different types of adverse events may be collected during different time frames in a clinical trial. Some adverse events are recorded only during specific portions of the trial, while others may be recorded throughout the duration of the trial [Ref. 35, 36, 37]. Time frame information could assist users of ClinicalTrials.gov in interpreting correctly and comparing the relative occurrence of adverse events across different clinical trials. Submission of this information is currently optional. Responsible parties provided time frame information with more than half of the results information submitted in 2012 for probable applicable clinical trials.

Collection approach: Collection approach information would indicate the type of approach taken to collect adverse event information, either ''systematic assessment'' or ''non-systematic assessment.'' Systematic assessment involves use of a specific method of ascertaining the presence of an adverse event, e.g., the use of checklists, questionnaires, or specific laboratory tests at regular intervals. Non-systematic assessment relies on spontaneous reporting of adverse events, such as unprompted self-reporting by participants. The approach used to assess adverse events affects comparability of information across clinical trials. For example, clinical trials using non-systematic assessment typically will record fewer adverse events than those using systematic assessment [Ref. 37]. Therefore, knowledge of the type of approach used to identify adverse events may help users of ClinicalTrials.gov to interpret differences in the rates of adverse events in different clinical trials. Submission of assessment type information currently is optional in ClinicalTrials.gov. Responsible parties who choose to submit this information select from the set of descriptors available in ClinicalTrials.gov (either ''systematic assessment'' or ''non-systematic assessment''). To simplify data entry, responsible parties are able to indicate the assessment type for the adverse event table as a whole or by each adverse event in the table. Of results for probable applicable clinical trials submitted in 2012, 76 percent included information about the approach to collecting some adverse events.

All-cause mortality information: An all-cause mortality table would consolidate information about all participant deaths from any cause following assignment to an arm, by arm, for the clinical trial. Although information related to deaths may be part of other clinical trial results information, the total number of deaths that occurred during the clinical trial might not be readily apparent (e.g., submitted adverse event information might indicate a number of subjects who experienced a myocardial infarction, but would not necessarily indicate how many of the subjects died from the event). Submission of all-cause mortality information would be consistent with some clinical trial reporting guidelines [Ref. 23, 38], but it might need to be accompanied by additional explanatory information that would assist users in interpreting it correctly, e.g., to indicate that deaths may not have been associated with the interventions studied in the clinical trial.

Standard vocabulary for adverse event terms. We also considered, but do not propose to require that adverse event terms be submitted according to a standard vocabulary. Although use of a single vocabulary might improve the comparability of adverse event data across trials represented in ClinicalTrials.gov, we do not believe it is reasonable to require responsible parties to submit adverse event data using a specific vocabulary. There is no agreed-upon standard adverse event vocabulary that is used in collecting and categorizing adverse event data for the full range of clinical trials. ClinicalTrials.gov currently allows responsible parties to indicate voluntarily any standardized vocabulary they have used when collecting adverse event data. Examination of the data voluntarily provided to date confirms that various versions of MedDRA are widely used by the pharmaceutical industry as the source of adverse event terms, but not by other entities (e.g., device manufacturers, non-industry organizations) that sponsor and conduct clinical trials. Other organizations use a variety of vocabularies, including SNOMED CT, which is an HHS-required standard for certification of electronic

health record products, or use no standard vocabulary at all. A requirement to submit adverse event data using a particular vocabulary would add significantly to the data submission burden for any responsible party who had used a different (or no) standard terminology in collecting adverse event data. In addition, requiring data collected under one terminology to be converted to a different terminology for submission to the data bank would carry unacceptable risks of data loss or misrepresentation. Such conversion is also a potentially much more difficult and time-consuming task than assigning high-level organ system classes to individual adverse event terms. As an alternative, we considered proposing that a single standard vocabulary be used to submit adverse event data for all clinical trials that are initiated after some date in the future (e.g., 2017). We rejected this approach because we do not think there is sufficient consensus on a standard vocabulary that is suitable for the full range of applicable clinical trials, and because ideally, data submission standards should follow data collection standards.

We understand that adverse event data from individual clinical trials are inherently difficult to interpret or to compare with similar data from other trials of the same intervention. Many factors may contribute to differences in the adverse events data collected in different trials, including differences in patient populations, differences in the methods or duration of adverse events collection, or in the types of adverse events collected. In addition, adverse event information available in ClinicalTrials.gov for a clinical trial most likely will differ from the adverse event data included in published reports or FDA documents discussing the same clinical trial, which may contain information on only a subset of adverse events for specific trials or provide aggregated information from multiple clinical trials. To avoid confusion with adverse event information available from sources other than ClinicalTrials.gov and to assist ClinicalTrials.gov users with varying degrees of expertise in clinical trial design and data analysis in understanding the adverse event data contained in the data bank, we will include a prominent notice and explanation in ClinicalTrials.gov describing the types of adverse events that are listed in clinical trial records and how they might differ between clinical trials and from information available in other sources. In addition, we will consider steps such as (1) linking to and offering on the ClinicalTrials.gov site other resource materials describing issues that need to be considered when interpreting adverse event information (e.g., issues of attribution, participants at risk); (2) creating a default public display that highlights certain data (e.g., all serious adverse events and other adverse events with frequencies above a certain threshold, such as 20 percent); and (3) providing mechanisms to allow the user to customize the display (e.g., by adjusting the frequency threshold).

We invite comments on all aspects of our proposed requirements for submission of adverse events information for clinical trials, including: (1) The benefit and burden of the proposed modifications to the statutory default provisions, including the number of participants affected by adverse events at the organ system level for both serious adverse events and other adverse events; (2) the potential benefit and burden of the additional information considered but not included in the proposal, such as the number of occurrences of each serious adverse event (in addition to the number of participants affected by a serious adverse event), the number of occurrences of each serious adverse event considered causally related to the intervention(s) studied, the time frame for collecting adverse events, the collection approach (systematic vs. non-systematic), and all-cause mortality information; (3) ways to reduce the data submission burden without reducing the value of the data submitted; and (4) approaches to increasing standardization in the vocabularies used in submitting adverse event information. We also invite and encourage the submission of any other information on current practices for collection, attribution, and summarization of adverse event data that might help us to refine the proposed requirements for submission of summary adverse event information.

16. Privacy Considerations

We believe that, in general, the information submitted to ClinicalTrials.gov for the vast majority of applicable clinical trials subject to this proposed rule would pose no privacy concerns. Registration and results information submitted to ClinicalTrials.gov pursuant to this proposed rule would consist of summary level data only and would not contain personally identifiable information. It would consist of the same type of information that would be expected to be included in a journal article or other routine form of public scientific communication. In addition, participants would be aware that summary data would be posted at ClinicalTrials.gov. FDA regulations require that informed consent forms for applicable clinical trials of drugs and devices include a specific statement to inform potential participants that certain information about the clinical trial will be submitted to ClinicalTrials.gov, where it will be publicly posted [see 21 CFR § 50.25(c)].

We also believe that in most cases it would not be possible to re-identify individuals who participated in a clinical trial based on the data submitted to ClinicalTrials.gov. For clinical trials of common diseases, or that recruit large numbers of participants, and/or recruit participants from multiple locations, the summary information submitted to ClinicalTrials.gov would be unlikely to contain characteristics that would enable re-identification of study participants. Even the information submitted for small trials with limited numbers of sites and few study participants would, in general, provide no clear basis for re-identification.

The risk of re-identification could be greater in particular types of clinical trials, such as small clinical trials that study treatments for rare diseases and have few recruitment sites or that recruit subjects from only small, well-defined populations. For some such clinical trials, we believe that a responsible party could submit required results information in a way that minimizes opportunities for re-identification. For example, if a trial of a rare disease recruits a participant of 90 years or more, the responsible party could consider submitting demographic information by grouping subjects into broader age categories or providing the mean age of all subjects in each arm of the trial, rather than breaking out the data for that one subject.

In those situations in which a responsible party believes results information could not be submitted in a way that is consistent with this proposed rule without risk of re-identification, the responsible party could alternatively request a waiver of results submission requirements, as permitted by section 402(j)(3)(H) of the PHS Act and proposed in § 11.54 of this rule. We believe such situations would be rare and such a waiver request would need to be evaluated on a case-by-case basis.

We invite public comment on other situations that might raise privacy concerns and on other approaches that we could propose to address them in a

way that is consistent with the requirements of section 402(j) of the PHS Act.

D. Effective Date/Compliance Date

1. Effective Date

We propose that the effective date of these regulations be established as 45 days after the date on which the final rule is published in the **Federal Register**. As of the effective date, the ClinicalTrials.gov system would be modified to be consistent with the final rule. As such, a responsible party that submits information into the data bank on or after the effective date must do so consistent with the final rule.

2. Compliance Date

We propose that the compliance date for these regulations be established as 90 days after the effective date of the rule. We interpret this to mean that a responsible party would have until the compliance date of the rule to come into compliance with the requirements of this proposed Part. Accordingly, by the compliance date of the rule: (a) Responsible parties for all applicable clinical trials initiated on or after, or ongoing as of, the effective date would have to comply with the clinical trial registration information requirements of proposed subpart B; (b) responsible parties for all applicable clinical trials required to submit clinical trial results information by a date that is on or after the effective date of the rule (including such trials whose completion dates were prior to the effective date of the rule, but for which results are due on or after the effective date of the rule under section 402(j)(3)(E) of the PHS Act) would have to comply with the clinical trial results information requirements of proposed subpart C; (c) responsible parties that make voluntary submissions of clinical trial information on or after the effective date of the rule would have to comply with proposed § 11.60 and any other applicable provisions of the final rule; and (d) responsible parties that submit clinical trial information to ClinicalTrials.gov, for both applicable clinical trials and clinical trials voluntarily submitted to the data bank under proposed § 11.60, on or after the effective date of the rule, would be required to update such clinical trial information in accordance with the requirements of proposed § 11.64(c).

Consistent with the foregoing, in instances in which submission of clinical trial registration or results information ordinarily would have been due between the effective date and the compliance date of the rule, the responsible party would have until the compliance date to submit the required clinical trial information. For example, if under this proposed part, clinical trial results information were due for an applicable clinical trial on a date that is 30 days after the effective date of the rule, the responsible party for that applicable clinical trial would have until the compliance date to submit such information. That said, because we propose to modify ClinicalTrials.gov consistent with the final rule as of the effective date of the rule, responsible parties seeking to come into compliance with the final rule after the effective date but prior to the compliance date would be able to do so.

We recognize that there will be situations in which the determination of one submission deadline will be conditioned upon an earlier submission deadline. In such situations, the Agency would consider the deadline pursuant to section 402(j) of the PHS Act and the final rule, notwithstanding the compliance date, as the applicable date for purposes of determining a subsequent deadline. For example, responsible parties that submit a certification to delay results submission under section 402(j)(3)(E)(v) of the PHS Act or proposed § 11.44(b)(1) must subsequently submit clinical trial results information no later than two years after the date of the certification. (See section 402(j)(3)(E)(v)(III) of the PHS Act and proposed § 11.44(b)(2).) If the deadline for the certification to delay results submission falls between the effective date and compliance date of the rule, then the responsible party would have until the compliance date to submit the certification. However, the subsequent deadline—i.e., the date by which clinical trial results information is due—would remain 2 years after the certification would have been due absent the compliance date.

We believe that the proposed 90-day delay between the effective date and the compliance date of the final rule would provide ample time for responsible parties of applicable clinical trials to come into compliance with the final rule. This proposed 90-day delay is the same number of days provided after the date of enactment of section 402(j) of the PHS Act for ongoing applicable clinical trials to submit registration information.

3. Registration Information

Clinical trial registration information submitted on or after the effective date of the rule would need to comply with the clinical trial registration information requirements of proposed subpart B. Furthermore, if an applicable clinical trial is ongoing as of the effective date of the rule and clinical trial registration information for that trial had been submitted prior to the effective date of the rule, the responsible party would need to submit any revised or additional registration information necessary to comply with proposed § 11.28 by the compliance date. This would help ensure that complete clinical trial registration information, as defined in this proposed rule, is available to the public for all ongoing applicable clinical trials subject to this proposed part. This also would ensure that certain information that was not previously required in order to register a clinical trial with ClinicalTrials.gov, but which is essential to the implementation of the proposed regulation, will be included in the data bank for all applicable clinical trials ongoing as of the effective date of the rule.

By contrast, if an applicable clinical trial reached its completion date prior to the effective date of the rule, and thus would not be ongoing as of the effective date of the rule, the responsible party would not be required to submit the additional registration information that would be required by proposed § 11.28. The responsible party would nevertheless be expected to have provided, at minimum, registration information containing all of the data elements specified in section 402(j)(2)(A)(ii) of the PHS Act, as they were available in ClinicalTrials.gov at the time of registration, namely, Brief Title, Brief Summary, Primary Purpose, Study Design, Study Phase (for an applicable drug clinical trial), Study Type, Primary Disease or Condition or Focus of the Study, Intervention Name, Intervention Type, Study Start Date, Completion Date (listed in ClinicalTrials.gov as ''Study Completion Date''), Target Number of Subjects (listed in ClinicalTrials.gov as ''Enrollment''), Primary and Secondary Outcome Measures, Eligibility Criteria, Gender, Age Limits, Whether the Trial Accepts Healthy Volunteers (listed in ClinicalTrials.gov as ''Accepts Healthy Volunteers?''), Overall Recruitment Status, Individual Site Status, Availability of Expanded Access (for an applicable drug clinical trial) (listed in ClinicalTrials.gov as ''expanded access record''), Name of the Sponsor, Responsible Party by Official Title (listed in ClinicalTrials.gov as ''Responsible Party Information''), Facility Name and Facility Contact Information (either facility-specific or central contact information), Unique Protocol Identification Number, Secondary ID, IND/IDE number (listed in ClinicalTrials.gov as ''IND/IDE Protocol''), and Record Verification

Date. We also would expect the responsible party to have updated these data elements as necessary, consistent with the section 402(j)(4)(C) of the PHS Act. For example, for each of the applicable clinical trials in this category, we would expect that the Completion Date data element would have been updated not later than 30 calendar days after the completion date of the clinical trial to reflect the ''actual'' completion date of the clinical trial. See section 402(j)(4)(C)(i)(IV) of the PHS Act.

We recognize that the data elements listed in the previous paragraph do not provide sufficient information for the responsible party to demonstrate (or for the Agency to determine) in all cases whether a clinical trial that was registered in ClinicalTrials.gov prior to the effective date of the rule meets the definition of an applicable clinical trial and thus whether results information was required to be submitted. The need to determine whether a clinical trial is an applicable clinical trial, in all cases, is one of the reasons we have proposed in § 11.28 to require the submission of several additional data elements as part of clinical trial registration information, e.g., Single Arm Controlled as part of Study Design (for single-armed studies); Product Manufactured in U.S.?; and U.S. FDA Approval, Clearance, or Licensure Status. Responsible parties may voluntarily submit such additional data elements for clinical trials that were registered and reached their completion dates before the effective date of this rule. Submission of this information will enable the clinical trial record to indicate whether or not the clinical trial is an applicable clinical trial subject to section 402(j) of the PHS Act.

4. Results Information

We interpret the approval status of a product studied in an applicable clinical trial (i.e., either ''unapproved, unlicensed, or uncleared'' or ''approved, licensed, or cleared'') to be the approval status of the product on any given date. For example, if a drug being studied in an applicable clinical trial was unapproved as of the completion date, at that time, the applicable clinical trial would be of an unapproved product. However, if and when the study drug receives FDA approval (for any indication), the applicable clinical trial would be of an approved product as of the date of FDA approval.

(a) Applicable clinical trials that reach their completion dates on or after the effective date of the rule. Responsible parties would be required to submit clinical trial results information specified in proposed subpart C for all applicable clinical trials that are required to be registered in ClinicalTrials.gov under section 402(j) of the PHS Act or this proposed rule that reach their completion dates on or after the effective date of the rule. This requirement would apply to applicable clinical trials of unapproved, unlicensed, or uncleared products as well as approved, licensed, or cleared products.

(b) Applicable clinical trials that reach their completion dates prior to the effective date of the rule—approved, licensed, or cleared products. In general, the responsible party for an applicable clinical trial of an approved, licensed, or cleared product that reaches its completion date prior to the effective date of the rule would not be required to submit the additional clinical trial results information required under proposed § 11.48 if the responsible party has already submitted the clinical trial results information required under section 402(j)(3)(C) of the PHS Act. This reflects the Agency's decision, as further described in section III.C.9 of this preamble, not to exercise its authority under section 402(j)(3)(D)(iv)(II) of the PHS Act to require ''the clinical trial information described in [section 402(j)(3)(D)(iii) of the PHS Act] . . . to be submitted for an applicable clinical trial for which the clinical trial information described in [section 402(j)(3)(C) of the PHS Act] is submitted to the registry and results data bank before the effective date of the regulations.'' We interpret the phrase ''is submitted'' to mean ''is required to be submitted,'' in order to make clear that this provision would also apply to those responsible parties who were required to submit results under section 402(j)(3)(C) of the PHS Act, but failed to do so.

There are three scenarios in which we propose to require the responsible party for an applicable clinical trial of an approved, licensed, or cleared product that reaches its completion date prior to the effective date of the rule to submit the additional clinical trial results information under proposed § 11.48:

First, in certain cases, an applicable clinical trial may reach its completion date prior to the effective date of the rule, but the clinical trial results information is neither due nor submitted until after the effective date of the rule. For example, under section 402(j)(3)(E)(i) of the PHS Act, clinical trial results information is due for an applicable clinical trial of an approved, licensed, or cleared product not later than 1 year after the completion date of the trial. Thus, if clinical trial results information is submitted after the effective date of the rule, consistent with this deadline, the responsible party would be required to submit the clinical trial results information required by proposed § 11.48.

Second, there may be situations consistent with proposed § 11.44(a)(2) in which an applicable clinical trial of an approved, licensed, or cleared product reaches its completion date prior to the effective date of the rule, has partial results information (i.e., primary outcome measures) submitted before the effective date of the rule, but has other partial results information (i.e., secondary outcome measures) that is neither due nor submitted until on or after the effective date of the rule. The Agency proposes to exercise its authority under section 402(j)(3)(D)(iv)(II) of the PHS Act in situations when partial results are due on or after the effective date of the rule to require the responsible party to submit clinical trial results information under proposed § 11.48 for all outcome measures, including primary outcome measures submitted prior to the effective date of the rule. We make this proposal so that, for any such trial, the data bank ultimately will contain the same required data elements for both primary and secondary outcome measures.

Third, as a result of modifications that would be made to the ClinicalTrials.gov data bank upon implementation of the final rule, the responsible party would be required to submit clinical trial results information as specified in proposed § 11.48 for any applicable clinical trial of an approved, licensed, or cleared product for which results information was required to be submitted under section 402(j)(3)(C) of the PHS Act prior to the effective date of the rule, but for which the responsible party failed to do so. Such responsible parties would be required to submit the clinical trial results information specified in § 11.48, even though only the clinical trial results information specified in section 402(j)(3)(C) of the PHS Act would have been required had results information been submitted on time. Accordingly, we are electing to exercise our authority under section 402(j)(3)(D)(iv)(II) of the PHS Act to require such responsible parties of applicable clinical trials of approved, licensed, or cleared products to submit the additional results data elements specified in proposed § 11.48. As discussed in section III.C.9 of this preamble, section 402(j)(3)(D)(iv)(II) of the PHS Act provides that the Secretary shall by regulation determine ''whether the clinical trial information described

in [section 402(j)(3)(D)(iii) of the PHS Act] should be required to be submitted for an applicable clinical trial for which the clinical trial information described in [section 402(j)(3)(C) of the PHS Act] is submitted to the registry and results data bank before the effective date of the regulations.'' We interpret the phrase ''is submitted'' to mean ''is required to be submitted,'' in order to make clear that this provision would also apply to those responsible parties who were required to submit results information under section 402(j)(3)(C) of the PHS Act, but failed to do so.

(c) Results information for applicable clinical trials that reach their completion dates prior to the effective date of the rule—unapproved, unlicensed, or uncleared products. With respect to applicable clinical trials of unapproved, unlicensed, or uncleared products that reach their completion dates prior to the effective date of the final rule, whether clinical trial results information is required under this proposed rule would depend on whether the product under study gets approved, licensed, or cleared. If the drug or device under study in an applicable clinical trial that reached its completion date prior to the effective date of the rule is never approved, licensed, or cleared by FDA, then submission of results information would not be required. However, if the drug or device under study is subsequently approved, licensed, or cleared after the effective date of the rule, then, consistent with section 402(j)(3)(E)(iv) of the PHS Act, clinical trial results information required by proposed § 11.48 would be due by the earlier of 1 year after the completion date or 30 calendar days after the date of initial FDA approval, licensure or clearance. In addition, the clinical trial results information under § 11.48 would be required if results were due and submitted after the effective date of this proposed rule.

5. Voluntary Submissions

If on or after the effective date, a responsible party voluntarily submits clinical trial information for a clinical trial that is not an applicable clinical trial, or that is an applicable clinical trial but is not required to register in ClinicalTrials.gov under section 402(j)(2)(C) of the PHS Act, the voluntary submissions provision of section 402(j)(4)(A) of the PHS Act and proposed § 11.60 apply to that submission, regardless of the completion date of such trial.

6. Updates and Corrections to Clinical Trial Information

With respect to clinical trial registration information or clinical trial results information that is due on or after the effective date of the rule, the Agency intends to require responsible parties to update such information, in accordance with proposed § 11.64.

With respect to clinical trial information that is due prior to the effective date of the rule, the Agency intends to continue requiring responsible parties to update such information in accordance with the requirements set forth in section 402(j)(4)(C) of the PHS Act. Because responsible parties that submitted clinical trial information to the data bank prior to the effective date of the final rule would have submitted only those data elements required under sections 402(j) of the PHS Act, which excludes any additional data elements required under the final rule, they would be required to update only that information that was required to be submitted prior to the effective date of the rule and only to the extent required under section 402(j)(4)(C) of the PHS Act.

In the event that a clinical trial reaches its completion date prior to the effective date of the rule but clinical trial results information is due after the effective date of the rule, the responsible party would be required to update the clinical trial registration information in accordance with the requirements of section 402(j)(4)(C) of the PHS Act, but it would be required to update the clinical trial results information submitted after the effective date in accordance with the requirements of proposed § 11.64(c). As discussed earlier in this section, a responsible party of a clinical trial that is registered but ongoing as of the effective date of the rule would be required to submit registration information consistent with proposed § 11.28 by the compliance date of the rule; consistent with this approach, responsible parties would be required to update the clinical trial registration information for such trials in accordance with the requirements of proposed § 11.64(c).

Notwithstanding the foregoing, if a responsible party becomes aware of previously submitted clinical trial information that contains errors that need to be corrected or that may have been falsified, the Agency proposes to require responsible parties to correct such previously submitted clinical trial information in accordance with proposed § 11.66(c), regardless of when such clinical trial information was submitted to data bank. We believe our proposed approaches outlined in this part balance the differing positions expressed in comments made at the public meeting. We invite public comment on the advantages and disadvantages of this proposed approach and on other approaches that might be considered by the Agency in establishing the effective date and the compliance date.

IV. Detailed Description of This Proposed Rule

Proposed Subpart A, General Provisions, sets forth the purpose of the regulations; to whom the regulations apply; the form and manner for submission of clinical trial information; the requirement that the submission of information under this part be truthful and not false or misleading; and the definitions applicable to this part.

Proposed Subpart B, Registration, sets forth the requirements related to clinical trial registration information. It delineates who must submit clinical trial registration information; which applicable clinical trials must be registered in ClinicalTrials.gov; when clinical trial registration information must be submitted; where clinical trial registration information must be submitted; what constitutes clinical trial registration information; and by when NIH will post submitted clinical trial registration information.

Proposed Subpart C, Results Submission, addresses the submission of clinical trial results information. It delineates who must submit clinical trial results information for applicable clinical trials; which applicable clinical trials are subject to the results submission requirement; when the clinical trial results information must be submitted; where and in what format clinical trial results information must be submitted; what constitutes clinical trial results information; by when NIH will post submitted clinical trial results information; and under what circumstances a waiver of the regulations will be granted.

Proposed Subpart D, Additional Submissions of Clinical Trial Information, sets forth the requirements and procedures for voluntary submissions of clinical trial information for clinical trials of FDA-regulated drugs and devices, submissions required to protect the public health, and updates to previously-submitted clinical trial registration and results information.

A detailed discussion of this proposed rule, its statutory basis, and the purpose of its provisions follows.

A. General Provisions—Subpart A

1. What is the purpose of this part—§ 11.2

As set forth in proposed § 11.2, the purpose of this part is to implement section 402(j) of the PHS Act [42 U.S.C. 282(j)], by providing requirements and procedures for the submission of clinical trial information for certain applicable clinical trials and other specified clinical trials to the Director of NIH to be made publicly available through ClinicalTrials.gov, the Internet-accessible clinical trial registry and results data bank established by NLM at *http://www.clinicaltrials.gov.*

2. To whom does this part apply?—§ 11.4

Proposed § 11.4(a) specifies that this proposed rule applies to any person or entity that is considered to be the ''responsible party'' for an applicable clinical trial that is required to be registered under § 11.22 or a clinical trial for which clinical trial information is submitted voluntarily under § 11.60. The responsible party would be either the sponsor of the clinical trial or a principal investigator who meets the criteria specified in proposed § 11.4(c)(2) and has been so designated by the sponsor. (See proposed § 11.4(c).) Proposed § 11.22 specifies which applicable clinical trials are required to submit registration information to ClinicalTrials.gov (i.e., applicable drug clinical trials and applicable device clinical trials that were initiated after September 27, 2007, or that were initiated on or before September 27, 2007, and ''ongoing'' (as such term is defined by this proposed rule) on December 26, 2007, consistent with section 402(j)(2)(C) of the PHS Act. Proposed § 11.60 specifies requirements for voluntary submissions of clinical trial information for applicable clinical trials that are not required to register under section 402(j) of the PHS Act (e.g., because they were completed prior to September 27, 2007), and for clinical trials that do not meet the definition of an applicable clinical trial. The voluntary submission of clinical trial registration or results information for such clinical trials, triggers a requirement to submit clinical trial registration or results information for certain other trials, as required by section 402(j)(4)(A) of the PHS Act. (*See* proposed § 11.60(a)(2)(ii)).)

In no case would this proposed rule apply to the sponsor or principal investigator or other individual or entity associated with a clinical trial of a health intervention that is not subject to FDA jurisdiction. Although section 402(j)(4)(A) of the PHS Act directs the NIH to permit ''[v]oluntary submissions'' of clinical trial information for ''a clinical trial that is not an applicable clinical trial or that is an applicable clinical trial that is not subject to'' the registration provisions of section 402(j)(2) of the PHS Act, we interpret section 402(j) of the PHS Act and thus this proposed rule as not applying to anyone who submits information to ClinicalTrials.gov about trials of interventions that are not subject to FDA jurisdiction under sections 505, 510(k), 515, 520(m), or 522 of the FD&C Act, or section 351 of the PHS Act. Moreover, we interpret section 402(j) of the PHS Act and thus this proposed rule as not applying to anyone who submits information to ClinicalTrials.gov for a study that is neither an interventional clinical trial nor a pediatric postmarket surveillance of a device as defined in this part (e.g., for a study that is an observational study), even if it involves a drug or device subject to sections 505, 510(k), 515, 520(m), or 522 of the FD&C Act, or section 351 of the PHS Act. Consistent with other statutory authorities of the NIH and long-standing practice, however, ClinicalTrials.gov may, and does, accept registration and results information on clinical studies and interventions that are not subject to the requirements of section 402(j) of the PHS Act and this proposed rule.

Proposed § 11.4(b) implements section 402(j)(1)(B) of the PHS Act, which provides that the Secretary ''shall develop a mechanism by which the responsible party for each applicable clinical trial shall submit the identity and contact information of such responsible party to the Secretary at the time of submission of clinical trial [registration] information.'' Proposed § 11.4(b) provides that the responsible party's identity and contact information must be included as part of the clinical trial information that is submitted in accordance with subpart B and updated in accordance with § 11.64(b)(1)(ix) and (x). We propose in § 11.28(a)(4)(vii), to require submission of a data element entitled Responsible Party Contact Information that, as specified in proposed § 11.10(b)(38) includes the name, official title, organizational affiliation, physical address (i.e., street address), mailing address, phone number, and email address of the responsible party. To minimize redundant data entry, we will provide a mechanism for the responsible party to indicate if the mailing address is the same as the physical address. In those cases in which the responsible party is an organization, as opposed to an individual, we would require the name and official title to correspond to a designated contact person for the organization. As described in section IV.B.4(a) of this preamble, if the responsible party is an individual, we intend to make the name of responsible party publicly available in the data bank, but we do not propose to make the other contact information publicly available (i.e., the physical address, mailing address, phone number, and email address). The other contact information will be used for internal administrative processes (e.g., for necessary communications). We note that the official title and organizational affiliation of the responsible party will also be made publicly available as part of the Responsible Party, By Official Title data element, which is required to be submitted to ClinicalTrials.gov at the time of registration. See section 402(j)(2)(A)(ii)(III)(bb) of the PHS Act.

Proposed § 11.4(c) outlines procedures for determining the responsible party for each applicable clinical trial or other clinical trial subject to this part. We believe that there must be one (and only one) responsible party for each applicable clinical trial or other clinical trial. Absent a responsible party, the objectives of registration and results submission cannot be met. Because the definition of responsible party under section 402(j) of the PHS Act specifies, first, that the sponsor will be the responsible party and, second, that the PI is the responsible party if delegated this role through a designation ''by a sponsor, grantee, contractor, or awardee,'' with regard to clinical trials, the Agency looks first to determine who is the sponsor of the clinical trial, consistent with the definition proposed in this part, and assumes that such individual or entity is the responsible party, unless the PI has been designated the responsible party in accordance with the procedure established in proposed § 11.4(c)(2). For a pediatric postmarket surveillance of a device that is not a clinical trial, the responsible party would be considered the entity whom FDA orders to conduct the pediatric postmarket surveillance of a device.

Proposed § 11.4(c)(1) specifies who will be considered the sponsor. The Agency believes that there must be a sponsor, as that term is used in section 402(j)(1)(A)(ix) of the PHS Act, for each clinical trial, and that there can be only one sponsor. Without a defined sponsor, there cannot be a responsible party for a clinical trial because responsible party is defined as either the sponsor or the

principal investigator who has been so designated by the sponsor. The proposed definition of sponsor in § 11.10(a), includes both a ''sponsor'' and a ''sponsor-investigator'' as those terms are defined in 21 CFR 50.3. Both definitions in 21 CFR 50.3 refer to the sponsor as, in part, the person or entity who ''initiates'' the clinical investigation. For purposes of this proposed rule, if a clinical trial is being conducted under an IND or IDE, the IND/IDE holder would be considered to be the individual or entity who initiated the clinical trial and, therefore, the sponsor, regardless of how the clinical trial is being funded. For clinical trials not conducted under an IND or IDE, the sponsor would be considered to be the person or entity who initiated the trial and would be identified as follows.

(1) Where the clinical trial is being conducted by an entity under a research assistance funding agreement such as a grant or sponsored research agreement, the funding recipient generally would be considered to be the initiator of the clinical trial, and therefore, the sponsor. This is because, as a general rule, when a clinical trial is funded in this manner, the funding recipient ''initiates'' the clinical trial process by, for example, submitting a funding proposal and designing the clinical trial.

(2) Where the clinical trial is being conducted by an entity under a procurement funding agreement such as a contract, the party obtaining the goods or services for its direct benefit or use (the funder) generally would be considered to be the initiator of the trial, and therefore, the sponsor. This is because, as a general rule, when a clinical trial is funded in this manner, it is the funder of the clinical trial that initiates the clinical trial process by, for example, contracting with another entity for that entity to conduct a clinical trial meeting the specifications of the funder.

(3) Where there is no funding agreement supporting the clinical trial, the person or entity who initiated the clinical trial by preparing and/or planning the clinical trial, and who has appropriate authority and control over the clinical trial to carry out the responsibilities under section 402(j) of the PHS Act and this proposed part would be the sponsor.

Proposed § 11.4(c)(2) establishes the procedures for designation of a principal investigator as the responsible party. Section 402(j)(1)(A)(ix) of the PHS Act defines the responsible party, as either ''the sponsor of the clinical trial (as defined in . . . 21 [CFR 50.3] (or any successor regulation);'' or, as ''the principal investigator of such clinical trial if so designated by the sponsor, grantee, contractor, or awardee. . .'' In order to give practical effect to this provision, we believe that, for any given applicable clinical trial, only one entity—the sponsor—can designate the PI as the responsible party. We believe that this interpretation is consistent with section 402(j) of the PHS Act because in many situations the sponsor of the clinical trial will also be a grantee, contractor, or awardee (e.g., in a situation in which there is no IND/IDE holder, and the sponsor is considered the ''initiator'' of the trial). In addition, interpreting this provision in a different manner could result in situations in which both a sponsor (e.g., an IND/IDE-holder) and a PI (designated by a separate grantee, contractor, or awardee) consider themselves the responsible party and submit information for the same clinical trial. This would not only increase the overall burden associated with registration, but more importantly would undermine the integrity of the data bank and potentially cause confusion to users of the system.

Section 402(j)(1)(A)(ix) of the PHS Act permits a PI to serve as a responsible party only if he or she ''is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under [this proposed part] for the submission of clinical trial information.'' Accordingly, if the PI does not meet the specified conditions for serving as the responsible party, the sponsor cannot designate the PI as the responsible party, and the sponsor must remain the responsible party. In proposed § 11.10(a) we define, for purposes of this part, the term principal investigator (PI) to mean ''the individual who is responsible for the scientific and technical direction of the study.'' We note that under section 402(j)(1)(A)(ix) of the PHS Act, in order to be designated the responsible party, the PI must be responsible for ''conducting the trial'' and must have ''access to and control over the data from the clinical trial.'' We interpret ''the trial'' to mean ''the entire trial,'' and ''the data'' to mean ''all of the data'', including data collected at all sites of a multi-site trial.

We wish to clarify our understanding of section 402(j)(3)(C)(iv) of the PHS Act, as it relates to whether a PI would be eligible to serve as the responsible party under this proposed part. Section 402(j)(3)(C)(iv) of the PHS Act requires the responsible party to indicate, as an element of clinical trial results information, whether there exist ''certain agreements,'' which are described as ''an agreement . . . that restricts in any manner the ability of the principal investigator, after the completion date of the trial, to discuss the results of the trial at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the trial.'' We do not view the presence of such an agreement as necessarily disqualifying a PI from serving as the responsible party. Rather, we view only those agreements that prevent the PI from performing the functions described in section 402(j)(1)(A)(ix)(II) of the PHS Act or from submitting clinical trial information or any updates to such information required by section 402(j) of the PHS Act and this proposed part as preventing the PI from serving as the responsible party.

To provide for the orderly implementation of section 402(j)(1)(A)(ix)(II) of the PHS Act, pursuant to which the sponsor may designate a PI as responsible party, and ensure that the PI has notice of the designation, we have proposed a process in § 11.4(c)(2) for designating a PI, as follows: the sponsor shall provide notice of the designation to the PI and obtain acknowledgement of the PI's responsibilities under this proposed part. We intend to continue to provide mechanisms in the PRS for the sponsor and the PI to indicate the designation and the acknowledgement, respectively. The designation by the sponsor is currently reflected in ClinicalTrials.gov by having the PI submit clinical trial information via the sponsor's organizational account (the sponsor must provide an account for the PI within the sponsor's PRS organizational account). The acknowledgement is reflected by having the PI list his/her name as the responsible party and indicate that he/she was designated as responsible party by the sponsor. This approach has been implemented in ClinicalTrials.gov since 2011.

If and when a designated principal investigator becomes unable to meet all of the requirements of a responsible party, proposed § 11.04(c)(3) outlines the mechanisms by which the sponsor would become the responsible party. This might occur if, for example, a principal investigator dies, retires, changes jobs, or turns control of the clinical trial data over to the sponsor.

We note that even if a sponsor designates a principal investigator as the responsible party for an applicable clinical trial registered under proposed § 11.22, there may be times when the sponsor would need to provide the principal investigator with certain

information in order for the principal investigator to meet his or her obligations as responsible party under section 402(j) of the PHS Act and/or this proposed part. For example, the sponsor would likely have to provide the principal investigator with information to describe an expanded access program for which information is required to be submitted and updated pursuant to proposed §§ 11.28(a)(2)(viii) and 11.64. In some cases, a principal investigator who is the responsible party would rely upon the sponsor to obtain information necessary to determine if the applicable clinical trial meets the criteria for delayed submission of results information under proposed §§ 11.44(b) or (c). Although we would expect a principal investigator who is a responsible party to request such information from the sponsor, we also would expect a sponsor who has designated a principal investigator as the responsible party to provide such information. A principal investigator who is not provided the information necessary to enable him or her to meet all of the requirements for submitting and updating clinical trial information would not meet the criteria set forth in proposed § 11.4(c)(2)(i) to serve as the responsible party. If the sponsor does not provide the principal investigator with the requisite information to meet the criteria under proposed § 11.4(c)(2)(i), the principal investigator cannot be designated as a responsible party and the responsible party designation either would remain with or revert back to the sponsor.

3. What are the requirements for the submission of truthful information?—§ 11.6

Section 402(j)(5)(D) of the PHS Act specifies that ''clinical trial information submitted by a responsible party under this subsection shall not be false or misleading in any particular.'' In addition, it is a prohibited act under section 301(jj)(3) of the FD&C Act to submit clinical trial information under section 402(j) of the PHS Act that is false or misleading in any particular under section 402(j)(5)(D) of the PHS Act. Other Federal laws also govern the veracity of information or claims submitted to the Federal Government, such as 18 U.S.C. 1001 (making it a crime to make certain false statements to the executive, legislative, or judicial branch of the U.S. Government) and 31 U.S.C. 3802 (referencing civil and potential administrative liability of persons making certain false claims to the U.S. Government). Thus, we propose in § 11.6(a) to require that ''[t]he clinical trial information submitted by a responsible party under this part shall not be false or misleading in any particular.'' In addition, proposed § 11.6(b) provides that ''[s]ubmission of false and/or misleading information would subject the responsible party to civil, criminal, and/or administrative liability under U.S. law.'' Specifically, all information submitted by a responsible party to ClinicalTrials.gov must be truthful, including information submitted voluntarily and other information that may not fall under the definition of clinical trial information, such as certifications for delayed submission and requests for good-cause extensions. Note, however, that this part does not require inclusion of information from any source other than the applicable clinical trial or other clinical trial that is the subject of the submission.

To help ensure that responsible parties are aware of this requirement and to provide an opportunity for them to attest to the veracity of the information at the time of submission, we propose in § 11.6(b) to require the responsible party, each time he or she submits clinical trial information or other information to ClinicalTrials.gov, to ''certify that, to the best of his or her knowledge, the information submitted is truthful and not misleading and that he or she is aware that the submission of false and/or misleading information would subject the responsible party to civil, criminal, and/or administrative liability under U.S. law.'' This requirement is similar to requirements to certify to the truthfulness of information about FDA-regulated products submitted to FDA, and we believe is an important component of efforts to help ensure that submitted information is not false or misleading, as required by section 402(j)(5)(D) of the PHS Act, 18 U.S.C. 1001, and 31 U.S.C. 3802. We plan to implement this requirement in ClinicalTrials.gov by integrating a certification statement into the mechanism for submitting information electronically through the Protocol Registration System. The requirement of proposed § 11.6 would be met by the responsible party making an attestation such as the following: ''I certify that the information I have submitted is, to the best of my knowledge, truthful and not misleading, and I am aware that the submission of false and/or misleading information would subject me to civil, criminal, and/or administrative liability under U.S. law.''

4. In what form and manner must clinical trial information be submitted?—§ 11.8

Proposed § 11.8 sets forth requirements for the form and manner of submitting clinical trial information to ClinicalTrials.gov. It specifies that information submitted under this proposed part must be submitted electronically to ClinicalTrials.gov in the form and manner specified at *http://prsinfo.clinicaltrials.gov.* No other form or manner of submission will be accepted. Proposed §§ 11.10, 11.28 and 11.48, specify the individual data elements of clinical trial information that must be submitted to ClinicalTrials.gov at the time of registration and results submission (and updated in accordance with proposed § 11.64), including the subelements that are considered to be part of a data element (e.g., proposed § 11.10 specifies that the Study Design data element includes subelements of Interventional Study Model, Number of Arms, Arm Information, Allocation, Masking, and Single Arm Controlled).

Sections IV.B.4 and IV.C.4 of this preamble describe the specific form and manner in which data elements and subelements would be required to be submitted to ClinicalTrials.gov. For some data elements and subelements, responsible parties would be required to submit information in the form of free-text; for other data elements and subelements, responsible parties would be required to select the best response from menus of options presented in ClinicalTrials.gov. Some menus would offer a fixed set of options without an ''other'' option; others would offer a prespecified set of options plus an ''other'' option. In most cases, responsible parties selecting the ''other'' option would be required to provide an additional free-text response to elaborate on their other selections. Some data elements without an ''other'' option would also include an optional free-text field in which responsible parties could voluntarily provide additional information about the option selected. The use of menu options is intended to promote the entry of data in a structured manner that allows users to search ClinicalTrials.gov and retrieve comparable information, consistent with the requirements of sections 402(j)(2)(B) and (3)(D)(v)(I) of the PHS Act.

Menu options have been used in ClinicalTrials.gov since its launch. They are routinely used to improve the quality and help ensure the completeness of data submitted to information systems. Their use can reduce typographical errors in data

entry and minimize the data entry burden on responsible parties by providing a set of predefined options for common entries. By standardizing the set of available responses, they also promote the use of consistent terminology across entries and can improve the ability of users to search the data bank and compare entries easily across clinical trials, consistent with the requirements of sections 402(j)(2)(B)(iv) and (3)(D)(v)(I) of the PHS Act.

In describing the registration and results information to be submitted to ClinicalTrials.gov, the preamble specifies whether information would be submitted as free text or as menu selections. For data elements with menu options, the preamble specifies the complete set of options proposed, including whether or not an ''other'' option would be offered. The choice of providing menu options versus free-text fields and the set of menu options offered for specific data elements and subelements are based on our experience in operating ClinicalTrials.gov and on comments received from users of ClinicalTrials.gov, including those who commented on the draft guidance documents that were issued in 2002 and 2004 [Ref. 3, 4] (see section II.A of the preamble) and the preliminary version of the results database and adverse event module that were available for testing beginning in the spring of 2008 (see section II.B. of this preamble).

We anticipate that, from time to time, we might make minor changes to the specific form and manner in which responsible parties would submit individual data elements and subelements to ClinicalTrials.gov. Such changes would not require a responsible party to submit different or more clinical trial information than is specified in this proposed rule, but would alter the way in which the information is entered, with the general aim of making sure the menu options contain the most relevant, useful, and convenient options for responsible parties and users of the system. For example, if the research community develops a new type of clinical trial design, we might expand the list of menu options under the Interventional Study Model subelement of the Study Design data element to include it. If we find that many of the free-text entries for the Why Study Stopped data element fall into a small number of categories, we might offer them as menu options (in addition to accepting free-text for ''other'' reasons) to reduce the burden of data entry and improve the consistency and comparability of responses across registered clinical trials. We would provide prior notice and seek public comment on any proposed changes to the form and manner of submitting clinical trial information, and any changes would ultimately be reflected in the ClinicalTrials.gov data entry system at *http://prsinfo.clinicaltrials.gov*.

We invite comment on the specific form and manner described in this proposed rule for submitting data elements and subelements of proposed clinical trial information, including comment on the benefits and burden associated with providing proposed data elements and subelements, whether proposed menu options are sufficient to accommodate the range of potential entries (e.g., for different trial designs), and whether ''other'' options are needed for additional data elements. We also invite comment on the proposed approach described in this section for modifying the form and manner of submitting clinical trial information over time.

We further note that to reduce the burden on responsible parties related to the submission of information to the data bank, ClinicalTrials.gov accommodates both interactive, online entry of information for a specific clinical trial and automated uploading of information that is prepared in a specified electronic format. Responsible parties submitting information on multiple clinical trials may upload information that is prepared as a batch submission. We expect this feature will be of interest to large entities (e.g., drug and device manufacturers) who might be the responsible party for multiple clinical trials. Additional information about submitting information to ClinicalTrials.gov is available at *http://prsinfo.clinicaltrials.gov*.

5. What definitions apply to this part?—§ 11.10

Proposed § 11.10 defines certain terms and data elements used in this proposed part. The terms defined in proposed § 11.10(a) includes terms explicitly defined in section 402(j) of the PHS Act (e.g., ''applicable clinical trial'' and ''responsible party''); terms used but not defined in section 402(j) of the PHS Act (e.g., ''clinical trial''); and terms not specifically found in section 402(j) of the PHS Act but which are important for implementing the statutory provisions. With respect to terms not defined in the statute, we propose definitions to fit within the proposed framework for the expanded data bank and for purposes of satisfying the statutory goals, clarifying the application and operation of this proposed rule, in particular as related to information to be submitted to ClinicalTrials.gov, and/or for convenience. We also reference some terms defined under the PHS Act and the FD&C Act and implementing regulations, as necessary.

In March 2009 the Agency provided an elaboration of its then-current thinking about the definitions of the terms ''applicable clinical trial,'' ''applicable device clinical trial,'' ''applicable drug clinical trial,'' and ''responsible party'' in a document entitled ''Elaboration of the Definitions of Responsible Party and Applicable Clinical Trial'' that was posted on the ClinicalTrials.gov Web site. The posted document invites comments on the elaborations, but no written comments were received by the Agency. We discuss below a number of the proposed definitions.

Adverse event is a term used but not defined in section 402(j)(3)(I) of the PHS Act to describe a certain category of clinical trial results information. Current FDA regulations define the term ''adverse event'' with respect to drugs, but not to devices. (FDA regulations for devices include a different but related term, ''suspected adverse device effect,'' that is discussed below in the definition of the term ''serious adverse event''). FDA regulations for IND safety reporting requirements that were issued on September 29, 2010 (see 75 FR 59935, Sept. 29, 2010) and took effect on March 28, 2011 define an adverse event as ''any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related'' (21 CFR 312.32(a)). In addition to defining the term ''adverse event,'' those FDA regulations have the additional purpose of identifying circumstances in which certain adverse events (such as those that are serious and unexpected and that also meet the definition of a ''suspected adverse reaction,'' meaning the adverse event must have a reasonable possibility of being caused by the drug) must be reported in an expedited fashion while the trial is ongoing.

Because this proposed rule includes a requirement to submit to ClinicalTrials.gov summary information about anticipated and unanticipated adverse events observed during a clinical trial (as well as a requirement to submit information about serious adverse events), regardless of attribution (i.e., whether or not the investigator believes they are related to the intervention(s)), our proposed definition cannot be limited to adverse events that are anticipated, are likely to have been caused by the drug or device (or other type of intervention used in the clinical

trial), or that have a reasonable possibility of being related to the intervention under study. Instead, the proposed definition of adverse event must include all adverse events regardless of possible attribution and regardless of whether they were anticipated.

The HHS Office for Human Research Protections (OHRP) has a definition of adverse event that covers drug, device, and other interventions and has the same scope of adverse events addressed by section 402(j) of the PHS Act, i.e., it includes both anticipated and unanticipated event(s) regardless of whether they are attributed to the intervention(s) studied in the clinical trial. As discussed in OHRP's ''Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events'' (January 2007), an adverse event means ''[a]ny untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research'' [Ref. 39]. The OHRP definition was adapted from the definition used by the International Conference on Harmonization (ICH) Guideline E6, Good Clinical Practice: Consolidated Guidance [Ref. 40], which was published by FDA as a guidance document in the **Federal Register** in 1997 (62 FR 25692, May 9, 1997). The definition, therefore, is consistent with international norms. Although the ICH Guidelines are intended to apply to pharmaceutical products, the OHRP definition is intended to apply broadly to research in humans that involves any type of intervention.

Our proposed definition of adverse event derives from the OHRP definition. We propose to define an adverse event as ''any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.'' This interpretation helps improve consistency in the submission of adverse event information for applicable device clinical trials and applicable drug clinical trials. It is consistent with, although not identical to, the definition of adverse event included in FDA's IND regulations. We invite public comment on this proposed definition.

Applicable clinical trial is the term used in section 402(j)(1)(A)(i) of the PHS Act to designate the scope of clinical trials that may be subject to the requirements to submit clinical trial registration and results information as specified in this proposed part. Not all applicable clinical trials are subject to clinical trial registration and results submission requirements. For example, an applicable clinical trial that reached its completion date on or before September 27, 2007, is not subject to registration under section 402(j) of the PHS Act, nor is an applicable clinical trial that was ongoing as of September 27, 2007, and reached its completion date prior to December 26, 2007. This proposed rule adopts the definition of applicable clinical trial from section 402(j)(1)(A)(i) of the PHS Act, which relies on two other terms defined in that section of the PHS Act and this proposed rule, namely applicable device clinical trial and applicable drug clinical trial. In addition, in proposed § 11.22(b), we propose an approach for determining whether a clinical study or trial meets the definition of an applicable clinical trial.

Applicable device clinical trial is the term used in section 402(j)(1)(A) of the PHS Act to designate the clinical trial of a device and FDA-ordered pediatric postmarket surveillance of a device for which clinical trial information must be submitted to ClinicalTrials.gov under section 402(j) of the PHS Act. The term ''device'' is defined in section 402(j)(1)(A)(vi) as ''a device as defined in section 201(h) of the [FD&C] Act.'' We have adopted this definition of ''device'' in proposed § 11.10. In addition, this proposed rule adopts, in § 11.10, the definition of applicable device clinical trial, as provided in section 402(j)(1)(A)(ii) of the PHS Act: ''(I) a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the [FD&C] Act against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and (II) a pediatric postmarket surveillance as required under section 522 of the [FD&C] Act.''

The first part of the definition in section 402(j)(1)(A)(ii)(I) defines a clinical study as an applicable device clinical trial if it meets the following four criteria: (1) It is a prospective clinical study of health outcomes; (2) it compares an intervention with a device against a control in human subjects; (3) the studied device is subject to section 510(k), 515, or 520(m) of the FD&C Act; and (4) it is other than a small clinical trial to determine the feasibility of a device or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes. Except as described below with regard to pediatric postmarket surveillances of a device, if a clinical investigation fails to meet one or more of these criteria, it would not be considered an applicable device clinical trial. We have considered the meaning of these criteria carefully and our interpretation follows.

(1) ''Prospective clinical study of health outcomes.'' First, we interpret the term ''clinical study,'' with respect to a device. We interpret ''clinical study'' with respect to a device to mean an investigation in which a device is used in one or more human subjects. For purposes of interpreting the term ''clinical study,'' we consider the term ''human subject'' to have the same meaning as the term ''subject,'' which is defined in FDA regulations as a ''human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease.'' (See 21 CFR 812.3(p).) For purposes only of the requirements under section 402(j) of the PHS Act and this proposed rule, the term ''human subject'' does not include de-identified human specimens (see [Ref. 41]). Note that we use the term ''participant'' interchangeably with ''human subject'' in this document.

The term ''study'' is often used interchangeably with the term ''investigation.'' As pertaining to devices, ''investigation'' is defined as ''a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device.'' (See 21 CFR 812.3(h).) Although FDA regulations pertaining to devices do not specifically define the term ''clinical investigation,'' that term is defined in FDA regulations pertaining to clinical investigations of drugs and biological products as ''any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects,'' where ''experiment'' is defined as ''any use of a drug except for the use of a marketed drug in the course of medical practice.'' (See 21 CFR 312.3.) In our view, these definitions can be applied to device trials by defining a ''clinical study of a device'' as ''any experiment in which a device is administered, dispensed to, or used involving, one or more human subjects,'' defining an ''experiment'' as ''any use of a device except for the use

of a marketed device in the course of medical practice,'' and using the definition of ''subject'' described above (from 21 CFR 812.3(p)). This interpretation helps improve consistency between definitions of the terms applicable device clinical trial and applicable drug clinical trial. In addition, our proposed interpretation of a ''clinical study'' of a device would include studies in which subjects are assigned to specific interventions according to a study protocol. Studies in which a device is used on a patient as part of routine medical care and not because of a study or protocol would not be considered ''clinical studies'' for purposes of this rulemaking. An example of studies that would not be considered clinical investigations include situations in which, after a device has been administered to a patient in the course of routine medical practice by a healthcare provider, a researcher not associated with the administration of the device reviews the records of the patients in order to assess certain effects, interviews the patients to assess certain impacts, or collects longitudinal data to assess health outcomes.

Second, turning to our interpretation of ''prospective,'' we consider a ''prospective'' clinical study to be any study that is not retrospective or, in other words, one in which subjects are followed forward in time from a well-defined point (i.e., the baseline of the study) or are assessed at the time the study intervention is provided. A ''prospective clinical study'' also may have non-concurrent (e.g., historical) control groups. An example of a retrospective study, and thus not an applicable device clinical trial, is a study in which subjects are selected based on the presence or absence of a particular event or outcome of interest (e.g., from hospital records or other data sources) and their past exposure to a device is then studied.

Third, we interpret ''of health outcomes.'' For purposes of the definition of applicable device clinical trial, a ''prospective clinical study of health outcomes'' is a clinical study in which the primary objective is to evaluate a defined clinical outcome directly related to human health. For example, a clinical study of a diagnostic device (such as an in vitro diagnostic (IVD)) in which the primary purpose is to evaluate the ability of the device to make a diagnosis of a disease or condition is related directly to human health and, therefore, would be considered a clinical study ''of health outcomes'' for purposes of this proposed rule.

(2) ''Comparing an intervention with a device against a control in human subjects.'' We interpret an ''intervention with a device'' to be one in which a device is used on a human subject in the course of a study. As stated above, the meaning of the term ''human subject'' is consistent with the definition of ''subject'' in 21 CFR 812.3(p), except that for purposes only of the requirements under this part, the term ''human subject'' does not include de-identified human specimens. We interpret the term ''intervention'' broadly, to include various techniques of using the device such as, among other things, device regimens and procedures and use of prophylactic, diagnostic, or therapeutic agents.

A clinical study is considered to ''compare an intervention with a device against a control in human subjects'' when it compares differences in the clinical outcomes, or diagnosis, between human subjects who received an intervention that included a device and human subjects who received other interventions, or no intervention (i.e., the control group). The intervention under study may be with a device that has never been cleared or approved or with a device that has been cleared or approved, regardless of whether the clearance or approval is for the indication being studied. Such controlled clinical studies include not only concurrent control groups, but also non-concurrent controls such as historical controls (e.g., literature, patient records, human subjects as their own control) or validated objective outcomes using objective performance criteria, by which we mean performance criteria based on broad sets of data from historical databases (e.g., literature or registries) that are generally recognized as acceptable values.

Expanded access protocols under section 561 of the FD&C Act, under which investigational devices are made available to individuals under certain conditions, generally are not controlled clinical investigations and therefore generally are not applicable device clinical trials. In those instances in which use of an investigational device in an expanded access program is controlled and the program otherwise meets the definition of an applicable device clinical trial, the expanded access program would be considered an applicable clinical trial and would be registered as such. Similarly, continued access protocols, under which an investigational device continues to be made available after completion of a controlled trial while a marketing application is being prepared or reviewed, are, by definition, not controlled clinical investigations and, therefore, not applicable device clinical trials.

(3) ''A device subject to section 510(k), 515, or 520(m)'' of the FD&C Act. A device is considered to be subject to section 510(k), 515, or 520(m) of the FD&C Act if any of the following is required before it may be legally marketed in the U.S.: (1) a finding of substantial equivalence under section 510(k) permitting the device to be marketed; (2) an order under section 515 of the FD&C Act approving a pre-market approval application for the device; or (3) a humanitarian device exemption under section 520(m) of the FD&C Act. Such devices that are considered to be subject to section 510(k), 515, or 520(m) of the FD&C Act include significant risk devices for which approval of an investigational device exemption (IDE) is required under section 520(g) of the FD&C Act; non-significant risk devices that are considered to have an approved IDE in accordance with 21 CFR 812.2(b); or devices that are exempt from the submission requirements of 21 CFR 812.

If a clinical study of a device (1) includes sites both within the U.S. (including any territory of the U.S.) and outside of the U.S., and (2) any of those sites is using (for purposes of the clinical study) a device that is subject to section 510(k), 515, or 520(m) of the FD&C Act, we would consider the entire clinical study to be an applicable device clinical trial, provided that it meets all of the other criteria of the definition under this part. However, a clinical study of a device that is being conducted entirely outside of the U.S. (i.e., does not have any sites in the U.S. or in any territory of the U.S.) and is not conducted under an IDE may not be a clinical study of a device subject to section 510(k), 515, or 520(m) of the FD&C Act, and thus not an applicable device clinical trial, depending on where the device being used in the clinical study is manufactured. If the device is manufactured in the U.S. or any territory of the U.S., and is exported for study in another country (whether it is exported under section 801(e) or section 802 of the FD&C Act), then the device is considered to be subject to section 510(k), 515, or 520(m) of the FD&C Act. If the device is manufactured outside of the U.S. or its territories, and the clinical study sites are all outside of the U.S. and/or its territories, then the device would not be considered to be subject to section 510(k), 515, or 520(m) of the FD&C Act.

(4) ''Other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome

measure relates to feasibility and not to health outcomes.'' Clinical studies designed primarily to determine the feasibility of a device or to test a prototype device are considered by the Agency to be clinical studies conducted to confirm the design and operating specifications of a device before beginning a full clinical trial. Feasibility studies are sometimes referred to as phase 1 studies, pilot studies, prototype studies, or introductory trials. Feasibility studies are not considered applicable device clinical trials under this proposed part.

The second part of the definition in section 402(j)(1)(A)(ii)(II) specifies that an applicable device clinical trial includes ''pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act.'' Postmarket surveillances can take many forms, from literature reviews to controlled clinical trials. Based on the statutory language, any pediatric postmarket surveillance under section 522 of the FD&C Act, regardless of its design, is an applicable device clinical trial.

Applicable drug clinical trial is the term used in section 402(j) of the PHS Act to designate a clinical trial involving a drug (including a biological product) for which clinical trial information must be submitted to ClinicalTrials.gov, if the trial is subject to the registration and results submission requirements under section 402(j) of the PHS Act. Section 402(j)(1)(A)(iii)(I) of the PHS Act provides the following detailed definition of the term applicable drug clinical trial: ''a controlled clinical investigation, other than a phase I clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of th[e] [PHS] Act.'' Sections 402(j)(1)(A)(iii)(II) and (III) of the PHS Act further clarify that the term ''clinical investigation'' has the meaning given in 21 CFR 312.3 (or any successor regulation) and ''phase I'' has the meaning given in 21 CFR 312.21 (or any successor regulation). We propose to adopt the statutory definition of this term, replacing ''phase I'' with ''phase 1,'' to be consistent with the numbering scheme used in FDA regulations (21 CFR 312.21). We provide additional elaboration of the interpretation of applicable clinical trial below.

We interpret the definition of applicable drug clinical trial under section 402(j)(1)(A)(iii) of the PHS Act as having four operative elements: (1) ''controlled''; (2) ''clinical investigation''; (3) ''other than a phase [1] clinical investigation''; and (4) ''drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of th[e] [Public Health Service] Act.'' A clinical investigation that meets all four elements is considered to be an ''applicable drug clinical trial.'' Conversely, a clinical investigation that does not meet one or more of these criteria would not be considered an applicable drug clinical trial. We have carefully considered these four criteria, and our interpretation follows in an order that facilitates the explanation.

(1) First, with regard to a ''drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of th[e] [Public Health Service] Act,'' proposed § 11.10 adopts the definition of the term ''drug'' in section 402(j)(1)(A)(vii) of the PHS Act as follows: ''drug as defined in section 201(g) of the [FD&C Act] or a biological product as defined in section 351 of th[e] [PHS] Act.'' In keeping with the requirements of the FD&C Act and section 351 of the PHS Act, a drug or a biological product is considered to be ''subject to section 505 of the [FD&C] Act or section 351 of th[e] [PHS] Act,'' as applicable, if it is the subject of an approved new drug application (NDA) or licensed biologics license application (BLA), or if an approved NDA or licensed BLA would be required in order for that drug or biological product to be legally marketed. A non-prescription drug that is or could be marketed under an existing over-the-counter (OTC) drug monograph (See 21 CFR 330–358) is not considered ''subject to section 505 of the [FD&C] Act.''

A drug or a biological product that is subject to section 505 of the FD&C Act or to section 351 of the PHS Act, and therefore would require an approved NDA or licensed BLA in order to be marketed legally, can be shipped for the purpose of conducting a clinical investigation of that product if an investigational new drug application (IND) is in effect. Drugs (including biological products) that are being studied under an IND are considered ''subject to section 505'' both because (in most situations) the drug being studied would need an approved NDA or licensed BLA to be marketed legally, and because INDs are issued by FDA pursuant to the authority in section 505(i) of the FD&C Act. However, whether a drug or biological product is subject to section 505 of the FD&C Act or section 351 of the PHS Act is a different question from whether a clinical investigator would need to obtain an IND from FDA before beginning to enroll human subjects in that clinical investigation. Therefore, a drug (or biological product) being studied in a clinical investigation can be subject to section 505 of the FD&C Act or section 351 of the PHS Act, even if a clinical investigation of that drug or biological product is ''IND exempt'' (i.e., does not require an IND because that clinical investigation falls within 21 CFR 312.2(b)). Hence, provided it meets all other criteria of the definition, a clinical investigation of a drug (including a biological product) can be an applicable drug clinical trial under section 402(j) of the PHS Act and this part, even if it does not require an IND. Furthermore, if a sponsor chooses to obtain an IND (issued under section 505 of the FD&C Act) for a clinical investigation of a drug (including a biological product) that is not otherwise subject to section 505 or to section 351 of the PHS Act, the sponsor, in so doing, agrees to regulation under section 505 of the FD&C Act, and that clinical investigation thus will be considered an applicable drug clinical trial, provided that it meets all other criteria of the definition under this part.

If a clinical investigation of a drug (including a biological product) (1) includes sites both within the U.S. (including any territory of the U.S.) and outside of the U.S., and (2) any of those sites is using (for purposes of the clinical investigation) a drug or biological product that is subject to section 505 of the FD&C Act or section 351 of the PHS Act, we would consider the entire clinical investigation to be an applicable drug clinical trial, provided that it meets all other criteria of the definition under this part. However, a clinical investigation of a drug (including a biological product) that is being conducted entirely outside of the U.S. (i.e., does not have any sites in the U.S. or in any territory of the U.S.) may or may not be a clinical investigation of a drug or biological product subject to section 505 of the FD&C Act or section 351 of the PHS Act, and thus not an applicable drug clinical trial, depending on where the drug (including biological product) being used in the clinical investigation is manufactured. If the drug (including a biological product) is manufactured in the U.S. or any territory of the U.S., and is exported for study in another country under an IND (whether pursuant to 21 CFR 312.110 or section 802 of the FD&C Act), the drug or biological product is considered to be subject to section 505 of the FD&C Act or section 351 of the PHS Act (as applicable), and the clinical investigation may be an applicable drug clinical trial, provided that it meets all other criteria of the definition under this part. If the drug (including a biological

product) is manufactured outside of the U.S. or its territories, the clinical investigation sites are all outside of the U.S., and the clinical investigation is not being conducted under an IND, the drug or biological product would not be considered to be subject to section 505 of the FD&C Act or section 351 of the PHS Act, and the clinical investigation would not be an applicable drug clinical trial.

(2) Second, with regard to ''clinical investigation,'' section 402(j)(1)(A)(iii)(II) of the PHS Act provides that ''clinical investigation'' has the meaning given that term in 21 CFR 312.3, which defines ''[c]linical investigation'' as ''any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects.'' The regulation further defines an ''experiment'' as ''any use of a drug except for the use of a marketed drug in the course of medical practice.''

The FDA definition of ''clinical investigation'' of a drug includes studies in which human subjects are assigned to specific interventions according to a protocol. However, a situation in which a drug is administered or provided to a patient as part of routine medical care and not under a study or protocol would not be considered a ''clinical investigation'' for purposes of this rulemaking. Examples of studies that might fall under this description include situations in which, after a drug has been administered to a patient in the course of routine medical practice by a healthcare provider, a researcher not associated with the administration of the drug reviews the records of the patients to assess certain effects, interviews the patients to assess certain impacts, or collects longitudinal data to track health outcomes. Similarly, a situation in which a healthcare provider only observes and records the effects of the use of a marketed drug in the course of his or her routine medical practice would not be considered a ''clinical investigation'' under this definition. Because these activities would not be considered ''clinical investigations'' under 21 CFR 312.3, they would not be considered applicable drug clinical trials under section 402(j) of the PHS Act and this proposed part. Accordingly, in the approach described below in § 11.22(b)(2), we consider an ''interventional'' study (or investigation) of a drug to be an applicable drug clinical trial.

(3) Third, with regard to ''controlled,'' we consider a controlled clinical investigation to be one that is designed to permit a comparison of a test intervention with a control to provide a quantitative assessment of the drug effect. The purpose of the control is to distinguish the effect of a drug from other influences, such as the spontaneous change in the course of the diseases, placebo effect, or biased observation. The control will provide data about what happens to human subjects who have not received the test intervention or who have received a different intervention. Generally, the types of controls that are used in clinical investigations are: (1) Placebo concurrent control; (2) dose-comparison control; (3) no intervention concurrent control; (4) active intervention concurrent control; and (5) historical control. (See 21 CFR 314.126(b).)

In our view, a clinical investigation designed to demonstrate that an investigational drug product is bioequivalent to a previously approved drug product, or to demonstrate comparative bioavailability of two products (such as for purposes of submitting an abbreviated new drug application under 21 U.S.C. 355(j) or a new drug application as described in 21 U.S.C. 355(b)(2)) is considered to be a controlled clinical investigation. In this case, the control generally would be the previously approved drug product. However, as discussed below, bioequivalent or comparative bioanalysis studies that fall within the scope of studies described in 21 CFR 320.24(b)(1), (2), and (3) share many of the characteristics of a phase 1 study and would be considered phase 1 trials (and thus not applicable clinical trials) in this proposed rule.

Similar to expanded access to investigational devices, as discussed above in the definition of applicable device clinical trial, the use of an investigational drug in an expanded access program under section 561 of the FD&C Act is generally not ''controlled,'' and generally does not meet the definition of a ''controlled clinical investigation.'' In those instances in which use of an investigational drug in an expanded access program is controlled and the program otherwise meets the definition of an applicable drug clinical trial, the expanded access program would be considered an applicable clinical trial.

(4) Fourth, with regard to the ''other than a phase [1] clinical investigation'' element, an applicable drug clinical trial is defined in section 402(j)(1)(A)(iii) of the PHS Act to exclude phase 1 clinical investigations, consistent with 21 CFR 312.21. Under 21 CFR 312.21(a)(1), a phase 1 study ''includes the initial introduction of an investigational new drug into humans. Phase 1 studies are typically closely monitored and may be conducted in patients or normal volunteer subjects. These studies are designed to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During phase 1, sufficient information about the drug's pharmacokinetics and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, phase 2 studies. The total number of subjects and patients included in phase 1 studies varies with the drug, but is generally in the range of 20 to 80.'' Under 21 CFR 312.21(a)(2), ''[p]hase 1 studies also include studies of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.'' Studies that are phase 1 studies under 21 CFR 312.21 are not applicable drug clinical trials. Studies that are phase 1/phase 2 studies are not considered phase 1 studies and may be applicable drug clinical trial if they meet the other specified criteria.

Under certain circumstances, a clinical investigation designed to demonstrate that an investigational drug product is bioequivalent to a previously approved drug product, or to demonstrate comparative bioavailability of two products (such as for purposes of submitting an abbreviated new drug application under 21 U.S.C. 355(j) or a new drug application as described in 21 U.S.C. 355(b)(2)) will be considered to be a phase 1 clinical investigation under 21 CFR 312.21 for purposes of determining whether a particular clinical trial is an applicable drug clinical trial under section 402(j)(1)(A)(iii) of the PHS Act. Although phase 1 clinical investigations are generally designed to fit sequentially within the development plan for a particular drug, and to develop the data that will support beginning phase 2 studies, 21 CFR 312.21(a) does not limit phase 1 trials to that situation. Bioequivalence or comparative bioavailability studies that fall within the scope of the studies described in 21 CFR 320.24(b)(1), (2), and (3) share many of the characteristics of phase 1 clinical investigations as described in 21 CFR 312.21(a), and therefore will be considered to be phase 1 trials for purposes of section 402(j) of the PHS Act. However, bioequivalence or comparative bioavailability trials that fall within the scope of 21 CFR 320.24(b)(4) do not share the characteristics of phase 1 trials as

described in 21 CFR 312.21(a), and thus would not be considered to be phase 1 trials for purposes of section 402(j) of this proposed part.

In addition, for purposes of implementing this proposed rule, we propose to treat certain clinical trials of combination products as applicable drug clinical trials. Combination products are defined in 21 CFR 3.2(e). A combination product is comprised of a drug and device; a biological product and device; a drug and biological product; or a drug, biological product, and device that, for example, are physically, chemically, or otherwise combined or mixed and produced as a single entity or are separate products packaged together in a single package or as a unit. (See 21 CFR 3.2(e)(1) and (2)). Because the definition of drug in proposed § 11.10 includes a biological product, a combination product under this proposed rule would always consist, in part, of a drug. For this reason, we propose to treat clinical trials of combination products that meet the definition in 21 CFR 3.2(e) as applicable drug clinical trials, for purposes of implementing this proposed rule, so long as the clinical trial of the combination product is a controlled clinical investigation, other than a phase 1 clinical investigation (as described in above), and the combination product is subject to sections 505 of the FD&C Act and/or section 351 of the PHS Act (as described above) and/or section 510(k), 515, or 520(m) of the FD&C Act (as described in the definition of an applicable device clinical trial). Such clinical trials of combination products would therefore be subject to the registration and results submission requirements, including requirements for posting clinical trial information, for applicable drug clinical trials as described in this proposed part. We believe this approach will provide clarity to responsible parties conducting clinical trials of combination products.

Approved drug is defined to mean ''a drug that is approved for any indication under section 505 of the FD&C Act or a biological product licensed for any indication under section 351 of the PHS Act.''

Approved or cleared device. Section 402(j)(2)(D)(ii)(II) of the PHS Act uses the phrase ''a device that was previously cleared or approved'' to refer to a subset of devices that, if studied in an applicable device clinical trial, would trigger certain requirements under this proposed part with respect to the submission and public posting of clinical trial information. Accordingly, we believe that it is helpful to define the term ''approved or cleared device.'' Specifically, we want to clarify that our definition of approved or cleared device refers to any device that has been approved or cleared under the applicable section of the FD&C Act for any indication, even if the applicable device clinical trial studies the device for an unapproved or uncleared use. Consistent with the reference in section 402(j)(2)(D)(ii) of the PHS Act to approval or clearance of a device under the designated sections of the FD&C Act, we propose to define an approved or cleared device as ''a device that is cleared under section 510(k) of the FD&C Act or approved under section 515 or 520(m) of the FD&C Act for any indication.''

Arm is defined to mean ''a pre-specified group or subgroup of human subjects in a clinical trial assigned to receive specific intervention(s) (or no intervention) according to a protocol.''

Clinical trial is defined to mean ''a clinical investigation or a clinical study in which human subjects are prospectively assigned, according to a protocol, to one or more interventions (or no intervention) to evaluate the effects of the interventions on biomedical or health-related outcomes.'' The proposed definition explicitly includes ''biomedical'' in addition to ''health-related'' outcomes because we have defined the term ''clinical trial'' to include phase 1 studies, which may measure physiological changes that are biomedical in nature but may not be related to health effects. We have defined the term ''clinical trial'' to include phase 1 studies, in part, because phase 1 studies may be voluntarily submitted under section 402(j)(4)(A) of the PHS Act. The restriction of the scope of this definition to clinical investigations or studies in which human subjects are prospectively assigned to interventions is intended to distinguish clinical trials (interventional studies) from observational studies, in which the investigator does not assign human subjects to interventions, but, for example, observes patients who have been given interventions in the course of routine clinical care. Observational studies may also include retrospective reviews of patient medical records or relevant literature.

Further, in terms of defining the scope of a clinical trial, we recognize that it is sometimes difficult to determine the boundaries of a single clinical trial when there are two or more closely related clinical trials. In general, a clinical trial has an explicit group of human subjects who are assigned to interventions based on a protocol. The data from these human subjects are assessed and analyzed based on a protocol. However, when two different clinical trials share the same protocol, but the groups of human subjects are different and the outcomes will be analyzed separately, then they should be considered separate clinical trials. This is distinct from a situation in which multiple sites of the same clinical trial follow the same protocol with different groups of human subjects, but the intention is to analyze the primary outcome measure(s) with pooled data from all of the study sites. When some (or all) human subjects from a clinical trial are offered the opportunity to participate in an additional clinical trial that was not part of the original protocol (e.g., a follow-on study), and that requires a separate consent process, it would be considered a separate clinical trial.

Clinical trial information is the term defined in section 402(j) of the PHS Act to designate those data elements that the responsible party is required to submit to ClinicalTrials.gov when registering or submitting results information for a clinical trial, as described in §§ 11.28 and 11.48 of this proposed rule, respectively. Section 402(j)(1)(A)(iv) of the PHS Act expressly provides that ''[c]linical trial information'' means ''those data elements that the responsible party is required to submit under paragraph (2) or under paragraph (3)'' of section 402(j) of the PHS Act. Paragraph (2) refers to registration requirements and paragraph (3) refers to results submission requirements. Section 402(j)(3)(I)(v) of the PHS Act also expressly provides that adverse event information included in the data bank pursuant to the paragraph (3)(I) ''is deemed to be clinical trial information included in such data bank pursuant to subparagraph (C).'' Therefore, for purposes of this proposed rule, clinical trial information means ''the data elements, including clinical trial registration information and clinical trial results information that the responsible party is required to submit to ClinicalTrials.gov under this part.''

Clinical trial registration information is defined to mean ''the data elements that the responsible party is required to submit to ClinicalTrials.gov under § 11.28.'' The full set of data elements under § 11.28 must be submitted in order to register under proposed subpart B.

Clinical trial results information is defined to mean ''the data elements that the responsible party is required to submit to ClinicalTrials.gov under § 11.48 or, if applicable, § 11.60(a)(2)(i)(B).'' The full set of data elements under § 11.48 must be submitted when providing results

information under proposed subpart C. Clinical trial results information includes the adverse event information set forth in proposed § 11.48(a)(4). We include adverse event information as part of clinical trial results information pursuant to section 402(j)(3)(I)(v) of the PHS Act, which indicates that the adverse event information included in the registry and results data bank under section 402(j)(3)(I) of the PHS Act ''is deemed to be clinical trial information included in [the] data bank pursuant to [section 402(j)(3)(C) of the PHS Act].'' As discussed in greater detail in section IV.D.1 of this preamble, if, under proposed § 11.60, a responsible party seeks to submit clinical trial results information voluntarily for a clinical trial for which clinical trial registration information specified in § 11.28(a) is not submitted, clinical trial results information is defined to include the data elements in proposed § 11.48(a) and the data elements set forth in proposed § 11.60(a)(2)(i)(B).

Comparison group is defined in this proposed rule to mean ''a grouping of human subjects in a clinical trial, other than an arm, that is used in analyzing the results data collected during the clinical trial.'' In some trials, results data are not analyzed according to the arms to which human subjects were assigned; the data may be combined into other groupings for analysis. For example, in a cross-over study, human subjects in one arm of a trial may receive intervention X for a period of time followed by intervention Y, while human subjects in another arm of the trial may receive intervention Y for a period of time followed by intervention X. In such studies, results data are often analyzed by intervention (e.g., results for human subjects when receiving intervention X versus results for human subjects when taking intervention Y), rather than by arm. When submitting results information to ClinicalTrials.gov under proposed § 11.48, we believe responsible parties should submit the data in the same way in which it was analyzed, whether by arm (as defined above) or by comparison group. We do expect that the set of comparison groups for a particular trial would account for all of the participants in the analysis.

Completion date is defined in section 402(j)(1)(A)(v) of the PHS Act as ''the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated.'' This term has particular significance because the responsible party is required to submit ''the expected completion date'' to ClinicalTrials.gov upon registration (See section 402(j)(2)(A)(ii)(I)(jj) of the PHS Act) and to submit clinical trial results information for certain applicable clinical trials not later than 1 year after the earlier of the estimated or the actual completion date, See sections 402(j)(3)(E)(i)(I)&(II) of the PHS Act (unless the deadline is delayed or extended using one of the mechanisms described in proposed § 11.44). For purposes of this proposed rule, we interpret ''expected completion date'' to be synonymous with ''estimated completion date.''

This proposed rule adopts the statutory definition of completion date with respect to applicable clinical trials that are clinical trials with one modification. If a clinical trial has multiple primary outcome measures, each with a different date on which the final human subject is examined or receives an intervention for purposes of final data collection, the ''completion date'' refers to the date upon which data collection is completed for all of the primary outcomes. While this approach may delay somewhat the submission and public availability of clinical trial results information for the earliest primary outcomes, we expect any such delays to be minimal. Most clinical trials registered at ClinicalTrials.gov to date specify only a single primary outcome, and those with multiple primary outcomes have measurement time frames that are relatively close in time. Moreover, the proposed approach avoids cases in which the submission of clinical trial results information would be required before data collection has been completed for all of the primary outcomes in a clinical trial and before all of the results data for the primary outcomes have been ''unblinded,'' a situation that could threaten the scientific integrity of the clinical trial. While a responsible party could request a good-cause extension of the results submission deadline in such a situation under proposed § 11.44(e), the proposed definition should reduce the number of good-cause extension requests that responsible parties might be expected to file. Submission of results data for all primary outcomes at the same time will also aid in the interpretation of clinical trial results information by providing users of ClinicalTrials.gov with a more comprehensive set of data from the clinical trial, rather than data for only some of the primary outcomes. Thus, for purposes of this proposed rule, completion date means ''for a clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated. In the case of clinical trials with more than one primary outcome measure with different completion dates, this term refers to the date upon which data collection is completed for all of the primary outcomes.''

We note that the current implementation of ClinicalTrials.gov uses the term ''primary completion date'' to refer to ''completion date,'' as defined in section 402(j)(1)(A)(v) of the PHS Act. This was done to alert those submitting data to ClinicalTrials.gov under section 402(j) of the PHS Act that the definition of completion date differs from that of the term, ''study completion date,'' which refers to the date on which the last subject makes the last visit as part of the clinical trial (commonly referred to as ''last patient, last visit'' or LPLV) and is also collected by ClinicalTrials.gov. To improve concordance with section 402(j) of the PHS Act and to be consistent with our proposed definition, ClinicalTrials.gov will begin to use the term completion date once the final regulations take effect. We will include a notice in ClinicalTrials.gov to alert responsible parties to this change in data element name.

For a pediatric postmarket surveillance of a device that is not a clinical trial, completion date means ''the date on which the final report summarizing the results of the pediatric postmarket surveillance is submitted to FDA.'' (See proposed § 11.10.)

Control or Controlled are terms used in sections 402(j)(1)(A)(ii)(I) and (iii)(I) of the PHS Act as part of the definitions of ''applicable device clinical trial'' and ''applicable drug clinical trial,'' respectively. For purposes of this proposed rule, the term ''controlled'' means, ''with respect to a clinical trial, that data collected on human subjects in the clinical trial will be compared to concurrently collected data or to non-concurrently collected data (e.g., historical controls, including a human subject's baseline data), as reflected in the pre-specified primary or secondary outcome measures.'' This is consistent with FDA regulations that define the related concepts of ''adequate and well-controlled studies'' for drugs (21 CFR 314.126(b)(1) and (2)) and ''a well-controlled clinical investigation'' for devices (21 CFR 860.7(f)). FDA has also adopted as guidance the International Conference on Harmonization E10: Choice of Control Group and Related Issues in Clinical Trials (ICH E10), which describes considerations to be

used in choosing a control group. In FDA regulations, the critical attribute of a well-controlled clinical trial, which is the intent of any controlled trial, is ''a design that permits a valid comparison with a control to provide a quantitative assessment'' of the effect of the investigational intervention. (See 21 CFR 314.126(b)(2).) The FDA regulations recognize several types of concurrent controls (e.g., active control) and the non-concurrent, historical control. This can refer to a control group for which data were collected at a different time or place but can also refer to a clinical trial in which subjects serve as their own controls (e.g., the clinical trial measures change from baseline).

Our proposed definition of controlled is consistent with the types of controls recognized by FDA and the ICH E10 guidance, but is potentially broader in that it does not require that the study be ''adequate,'' i.e., that the control allows a valid comparison of the two treatments. It is consistent in that it explicitly recognizes both concurrent and non-concurrent controls. We recognize that this interpretation may differ from common use of the term ''controlled'' by some researchers, who may consider only studies with concurrent controls to be ''controlled,'' but we believe it is important to maintain consistency with the approach of the FDA and ICH E10 and to include non-concurrent controls. Our definition of controlled is broader than that of ''well-controlled'' used by FDA and ICH E10 because FDA regulations and the ICH E10 guidance describe the more limited circumstances in which use of a non-concurrent control constitutes a ''well-controlled'' clinical trial, i.e., one that might serve to support marketing. Although FDA regulations state that historical controls are usually reserved for special circumstances, such as studies of a disease with ''high and predictable mortality'' (e.g., certain malignancies) or in which the effect of the drug is ''self-evident'' (e.g., anesthesia, cardioversion), our proposed definition of controlled would include all studies using an historical control, regardless of whether the study is of a disease with a ''high and predictable mortality'' or in which the effect of the drug is self-evident. Our proposed definition would encompass all studies and investigations with a placebo concurrent control, dose-comparison concurrent control, no treatment concurrent control, active treatment concurrent control, and historical control, but it would not reflect a consideration of the adequacy or appropriateness of the control or the adequacy of the study design, e.g., whether adequate steps were taken to minimize bias. Hence it would cover all trials that are controlled, using concurrent or non-concurrent controls, regardless of whether they would be considered ''well-controlled.''

Under our proposed definition, any clinical trial with two or more arms would be considered controlled because it would involve the comparison of data collected concurrently from different arms of the study. Some single-arm trials that meet the other components of the definition of an applicable clinical trial, e.g., not phase 1 or a feasibility study, could also meet this definition of controlled. These include the single-arm trials of FDA-regulated products that have as a stated objective in their protocol to evaluate a response rate to an intervention, to measure effectiveness of an intervention at specific endpoints, and/or to compare the effect of an intervention against an identified baseline. Thus, single-arm clinical trials that explicitly identify primary or secondary outcomes in the protocol that involve comparisons to historical data (including baseline data) would be considered controlled.

Enroll or Enrolled is a term used in section 402(j)(1)(A)(viii)(I) of the PHS Act as part of the definition of ''[o]ngoing'' and in 402(j)(2)(C)(ii) of the PHS Act as one of the criteria used to establish the deadline by which a responsible party is required to submit clinical trial registration information. For purposes of this proposed rule, the term ''enrolled'' means ''a human subject's agreement to participate in a clinical trial, as indicated by the signing of the informed consent document(s).'' (See proposed § 11.10.)

Human subjects protection review board is defined in § 11.10 of this proposed rule to mean an ''institutional review board (IRB) as defined in 21 CFR 50.3 and 45 CFR 46.102 (or any successor regulation), as applicable, or equivalent independent ethics committee that is responsible for ensuring the protection of the rights, safety, and well-being of human subjects involved in a clinical investigation and is adequately constituted to provide assurance of that protection.'' We propose to include this definition to clarify the scope of the review boards for which Human Subjects Protection Review Board Status must be submitted under proposed § 11.28 (see section IV.B.4(a)(4) of this preamble). For clinical trials conducted in the U.S. or under an IND or IDE, the term human subjects protection review board would mean an institutional review board, as defined in the cited regulations issued by the FDA and OHRP within HHS. For clinical trials conducted outside the United States or otherwise outside the scope of the regulations for institutional review boards, the term would refer to other independent ethics committees that are responsible for ensuring the protection of the rights, safety, and well-being of human subjects involved in a clinical investigation and are adequately constituted to provide assurance of that protection. This phrasing is consistent with, but not identical to, the definition of the term ''independent ethics committee,'' in FDA regulations for INDs (See 21 CFR 312.3). It is also consistent with longstanding use of the term ''human subjects protection review board'' at ClinicalTrials.gov, which instructed registrants to provide information about ''[a]ppropriate review boards[, including] an Institutional Review Board, an ethics committee or an equivalent group that is responsible for review and monitoring of this protocol to protect the rights and welfare of human research subjects.'' [Ref 50]

Interventional is defined in this proposed rule to mean, ''with respect to a clinical study or a clinical investigation that participants are assigned prospectively to an intervention or interventions according to a protocol to evaluate the effect of the intervention(s) on biomedical or other health related outcomes.'' We propose to define this term to distinguish interventional studies from observational studies, as those terms are used in the clinical research community. Observational studies include those in which a patient receives an intervention as part of routine medical care, and a researcher studies the effect of the intervention. They also include retrospective reviews of patient medical records or relevant literature, as may occur in a pediatric postmarket surveillance of a device. Interventional studies are those in which a researcher assigns subjects to specific interventions (or to no intervention) according to a study protocol for purposes of the investigation. For purposes of this part, we use the term ''clinical trial'' to refer to interventional studies to the exclusion of observational studies. (See the proposed definition of clinical trial). The term ''interventional'' is one of the responses that can be submitted as part of the Study Type data element that is included as clinical trial registration information under proposed § 11.28 and defined in § 11.10. Responsible parties must indicate whether a study being registered is ''interventional'' or

''observational,'' or is an expanded access program that does not meet the definition of an applicable clinical trial. A study that is designated as ''interventional'' can be an applicable clinical trial if it meets the other criteria for an applicable clinical trial that are specified in this part. (See the proposed definitions of applicable device clinical trial and applicable drug clinical trial). A study should be designated interventional if it meets the proposed definition even if the medical products being studied are being used in a manner considered to be the standard of care. A study that is designated ''observational'' can be an applicable clinical trial only if it is a pediatric postmarket surveillance of a device as defined in this part. (See the proposed definition of pediatric postmarket surveillance of a device).

NCT number is the term used in this proposed part to refer to the term ''National Clinical Trial number[,]'' which is used in section 402(j)(2)(B)(i)(VIII) of the PHS Act. Since its launch in 2000, ClinicalTrials.gov has assigned each submitted clinical trial record a unique identifier once the information has completed quality review procedures. While the identifier originally was called a National Clinical Trial number, that nomenclature was soon changed to ''NCT number'' in recognition of the fact that ClinicalTrials.gov also receives clinical trial information about trials being conducted in countries other than the United States. We propose to maintain the term ''NCT number'' in this part. NCT numbers are used in many contexts to refer to clinical trial records or other types of records (e.g., observational studies, expanded access programs) that are accepted by ClinicalTrials.gov. Under the ICMJE registration policy, for example, journals publishing original papers on the results of clinical trials require their authors to include in their manuscripts a unique identification number assigned by a recognized clinical trial registry as evidence that the trial has been registered in compliance with the ICMJE policy [Ref. 10]. For trials registered in ClinicalTrials.gov, this unique identifier is the NCT number. When published in journal articles, NCT numbers are also included in MEDLINE records and are searchable through PubMed [Ref. 42]. For purposes of this proposed rule, NCT number means ''the unique identification code assigned to each record in ClinicalTrials.gov, including a record for an applicable clinical trial, a clinical trial, or an expanded access program.'' The NCT number is assigned to clinical trials and expanded access records once registration information has been submitted to the Director and the Director's quality control process has been completed, with the exception that if a responsible party voluntarily submits only clinical trial results information under § 11.60(a)(2)(i)(B), the NCT number is assigned once complete clinical trial results information has been submitted to the Director and the Director's quality control process has been completed.

Ongoing is defined in this proposed rule in § 11.10 to mean, ''with respect to a clinical trial of a drug or a device and to a date, that one or more human subjects is enrolled in the clinical trial, and the date is before the completion date of the clinical trial.'' This definition is the same as the statutory definition except the term ''human subjects'' has been substituted for the term ''patients'' that is used in section 402(j)(1)(A)(viii) of the PHS Act. The reason for this change is that clinical trials may include healthy volunteers as well as human subjects who might be considered ''patients.''

With respect to a pediatric postmarket surveillance of a device, we define the term ''ongoing'' to mean ''a date between the date on which FDA approves the plan for conducting the surveillance and the date on which the final report is submitted to FDA.''

Outcome measure is defined in this proposed rule to mean ''a pre-specified measurement that will be used to determine the effect of experimental variables on the human subjects in a clinical trial.'' The experimental variables may be the specific intervention(s) used in the clinical trial or other elements of the clinical trial that vary between arms, e.g., diagnostic or other procedures provided to participants in different arms. In this proposed part, outcome measure refers to measurements taken on those human subjects who are enrolled in the clinical trial of interest. Although it is not uncommon to compare data derived from human subjects enrolled in a clinical trial with data derived from other sources (e.g., literature, other clinical trials), we believe that only measurements taken from participants in the clinical trial of interest should be submitted as results information to ClinicalTrials.gov. In our view, comparisons of such data with results data derived from other sources are more appropriately described in forums other than ClinicalTrials.gov (e.g., journal articles) where the other comparator can be explained in detail. Clinical trial information submitted for a clinical trial of interest would not describe the human subjects studied in another clinical trial (i.e., the clinical trial record would not contain baseline and demographic information about them, nor would it describe how they were allocated to arms of the clinical trial to receive interventions). See the definitions of primary outcome, measure and secondary outcome measure below.

Pediatric postmarket surveillance of a device is a term used in section 402(j)(1)(A)(ii)(II) of the PHS Act to describe a type of applicable device clinical trial. The term ''[a]pplicable device clinical trial'' includes ''a pediatric postmarket surveillance as required under . . . [section 522 of the FD&C Act].'' Pursuant to section 522, FDA defines the term ''postmarket surveillance'' as ''the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information about a marketed device.'' (See 21 CFR 822.3(h).) In Title III of FDAAA, Congress directed that the term ''pediatric,'' when used with respect to devices, refers to patients 21 and younger. (See Title III of FDAAA (''Pediatric Medical Device Safety and Improvement Act of 2007''), amending section 520(m) of the FD&C Act). Thus, for purposes of this proposed rule, the term pediatric postmarket surveillance of a device is defined to mean ''the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information conducted under section 522 of the [FD&C] Act about a marketed device that is expected to have significant use in patients who are 21 years of age or younger at the time of diagnosis or treatment. A pediatric postmarket surveillance of a device may be, but is not always, a clinical trial.'' (See proposed § 11.10.)

Primary outcome measure(s) is a term used, but not defined, in section 402(j) of the PHS Act. Section 402(j)(2)(A)(ii)(I)(ll) of the PHS Act expressly requires primary outcome measures to be submitted as a clinical trial registration information data element. In addition, section 402(j)(1)(A)(v) of the PHS Act defines the completion date in relation to the ''final collection of data for the primary outcome.'' Primary outcome measure(s) also expressly is required as a clinical trial results information data element by section 402(j)(3)(C)(ii) of the PHS Act. We believe this enables users of ClinicalTrials.gov to identify the pre-specified primary outcome measure(s) for the clinical trial submitted as part of the clinical trial registration information and to examine the results data collected for those outcome measures and submitted to the data bank as part

of clinical trial results information. We propose to define primary outcome measure to mean ''the outcome measure(s) of greatest importance specified in the protocol, usually the one(s) used in the power calculation. Most clinical trials have one primary outcome measure, but a clinical trial may have more than one . . .'' (See proposed § 11.10.) We note that for the purpose of this proposed rule, ''primary outcome'' has the same meaning as ''primary outcome measure.'' (See proposed § 11.10.) See also the discussion in part IV of this preamble regarding primary outcome measure as a clinical trial registration information data element in proposed § 11.28(a)(1)(xix) and as a clinical trial results information data element in proposed § 11.48(a)(3).

Principal Investigator (PI) is a term used in the definition of responsible party in section 402(j)(1)(A)(ix) of the PHS Act. For purposes of this proposed rule, principal investigator means ''the individual who is responsible for the scientific and technical direction of the study.'' (See proposed § 11.10.) This proposed definition uses terminology derived from 42 CFR 52.2, which defines principal investigator in the context of an NIH grant as ''the individual(s) judged by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program supported by the grant and who is or are responsible for the scientific and technical direction of the project.'' We have modified that definition to remove references to ''applicant organization'' and ''project or program supported by the grant'' that are specific to NIH-funded grants and would not necessarily apply to applicable clinical trials that are funded by industry or other non-governmental organizations. We use the term ''study'' in place of ''project'' because the projects of relevance to this rule would be clinical studies, whether clinical trials or pediatric postmarket surveillances of a device. We have also modified the definition in order to indicate that it applies to only a single individual. This is consistent with our interpretation that there cannot be more than one responsible party for a clinical trial. We would expect a principal investigator to have full responsibility for the treatment and evaluation of human subjects in the study and for the integrity of the research data for the full study. In keeping with this approach, an investigator for an individual site in a multi-site clinical trial would not be considered the PI unless he or she also has overall responsibility for the clinical trial at all sites at which it is being conducted. This interpretation is consistent with the requirement in section 402(j)(1)(A)(ix) of the PHS Act that a principal investigator may be a responsible party only if he or she is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the clinical trial results, and has the ability to meet all the requirements for the submission of clinical trial information under section 402(j) of the PHS Act and this proposed part.

We note that the PI of a grant awarded by a Federal Government agency that funds a clinical trial may not necessarily be the PI for that clinical trial for purposes of this proposed rulemaking. For example, the PI on a federal grant who has responsibility for only one site of a multi-site clinical trial (See, e.g., 42 CFR 52.2.) would neither have the requisite responsibility for conducting the entire trial nor the requisite access to data from all sites involved in the clinical trial, both of which are required by section 402(j) of the PHS Act and this proposed part in order to meet the definition of responsible party. Accordingly, the PI on such a grant would not be considered to be the responsible party for purposes of registering and submitting clinical trial results information under section 402(j) of the PHS Act and this proposed part.

Protocol is the document that describes the design of a clinical trial. It may be, and frequently is, amended after a clinical trial has begun. For purposes of this proposed rule, protocol means ''the written description of the clinical trial, including objective(s), design, and methods. It may also include relevant scientific background and statistical considerations.'' This proposed definition is derived from ICH E6(R1): Good Clinical Practice: Consolidated Guideline [Ref. 40], which defines the term as ''[a] document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents.'' The protocol generally addresses major statistical considerations, such as the number of human subjects required to provide adequate statistical power, but it may or may not include detailed information about the specific statistical analyses to be performed as part of the clinical trial. Such information may be contained in a separate statistical analysis plan.

Responsible party is the term used in section 402(j) of the PHS Act in order to refer to the entity or individual who is responsible for registering a clinical trial or a pediatric postmarket surveillance of a device that is not a clinical trial and for submitting clinical trial information to ClinicalTrials.gov. Consistent with the definition provided in section 402(j)(1)(A)(ix) of the PHS Act, this proposed rule defines the term ''responsible party'' to mean, ''with respect to a clinical trial, (i) the sponsor of the clinical trial, as defined in 21 CFR 50.3 (or any successor regulation); or (ii) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under this part for the submission of clinical trial information. For a pediatric postmarket surveillance of a device that is not a clinical trial, the responsible party is the entity whom FDA orders to conduct the pediatric postmarket surveillance of a device.'' Proposed procedures for determining which individual or entity meets the definition of responsible party are specified in § 11.4(c) and described in section IV.A.2 of this preamble.

Secondary outcome measure(s) is a term used, but not defined, in section 402(j) of the PHS Act. Section 402(j)(2)(A)(ii)(I)(ll) of the PHS Act expressly requires secondary outcome measures to be submitted as a clinical trial registration information data element, as a component of the outcome measures data element. In addition, secondary outcome measure(s) also is expressly required as a clinical trial results information data element by section 402(j)(3)(C)(ii) of the PHS Act. We believe this structure enables users of ClinicalTrials.gov to identify the pre-specified secondary outcome measures for the clinical trial submitted as part of the clinical trial registration information and to examine the results data collected for those outcome measures and submitted to the data bank as part of clinical trial results information. Our proposed definition of ''secondary outcome measure'' means ''an outcome measure that is of lesser importance than a primary outcome measure, but is part of a pre-specified plan for evaluating the effects of the intervention or interventions under investigation in a clinical trial. A clinical trial may have more than one secondary outcome measure.'' This definition is consistent with the WHO Trial Registration standard and ICMJE registration policies

[Ref. 10, 13]. We note that for the purpose of this proposed rule, ''secondary outcome'' has the same meaning as ''secondary outcome measure.''

The specification in proposed § 11.10 that a secondary outcome measure is ''specifically planned to be analyzed as part of the clinical trial'' is intended to help responsible parties differentiate between secondary outcome measures and tertiary or other lesser outcome measures that are more exploratory in nature. We consider secondary outcome measures to be those outcome measures (other than the primary outcome measures) that are not considered exploratory and for which there is a specific analysis plan. In general, the analysis plan would be specified in the protocol or statistical analysis plan, but protocols do not always contain detailed information about statistical analysis, and statistical analysis plans may not be complete at the time a trial is registered. Hence, the plan to analyze the secondary outcome measure may be expressed only in other formal trial documentation (e.g., a grant application, contract, or published journal article). We view outcomes measures that are not part of an analysis plan or are indicated to be exploratory as tertiary or lower level outcome measures that do not need to be submitted to ClinicalTrials.gov, but for which information may be submitted voluntarily. See discussion in sections IV.B.4 and IV.C.4 of this preamble, respectively, regarding secondary outcome measure(s) as a clinical trial information data element to be submitted at the time of registration following proposed § 11.28(a)(1)(xx) and at the time of results submission, following proposed § 11.48(a)(3).

Serious adverse event is a term used but not defined in section 402(j)(3)(I) of the PHS Act. Section 402(j)(3)(I)(iii)(I) of the PHS Act requires the submission to ClinicalTrials.gov of specific information about ''anticipated and unanticipated serious adverse events'' for applicable clinical trials of drugs as well as devices. In defining the term ''serious adverse event'' in its IND Safety Reporting regulations at 21 CFR 312.32(a), FDA considers an adverse event to be ''serious'' when, in the view of either the sponsor or the investigator, it ''results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.'' A ''serious adverse event'', as defined in 21 CFR 312.32(a), applies only in the context of drugs (including biological products). No fully equivalent term is defined in FDA regulations for medical devices. In 21 CFR 812.3(s), FDA defines an ''unanticipated adverse device effect'' as, in part, ''any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device'' that ''was not previously identified . . . in the investigational plan or application . . . or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.'' However, because it is restricted to unanticipated effects, we do not consider this definition sufficient to meet the statutory requirement in section 402(j)(3)(I)(iii) of the PHS Act for submission of serious adverse event information that encompasses both anticipated and unanticipated events. Although we are relying on an FDA drug regulation, we emphasize that ''serious adverse event,'' as defined for purposes of this proposed rulemaking, applies to both drugs and devices.

Therefore, for purposes of this rulemaking, we draw upon the FDA definition of ''serious adverse event'' in 21 CFR 312.32(a), because it more fully characterizes the criteria for ''other serious problems'' as well as ''any life-threatening problem'' or ''[d]eath.'' Our proposed rule defines serious adverse event to mean ''an adverse event that results in any of the following outcomes: death, a life-threatening adverse event as defined in 21 CFR 312.32 (or any successor regulation), inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the human subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of a substance use disorder.'' We use the phrase ''a substance use disorder'' instead of the phrase ''drug dependency or drug abuse,'' which is used in the FDA definition, for consistency with the latest version (fifth edition) of the Diagnostic and Statistical Manual of Mental Disorders (DSM V). By referring to adverse events (and thus the definition of that term in this proposed part), our proposed definition of serious adverse event is broader than the FDA definition of serious adverse event in 21 CFR 312.32(a) because it encompasses any untoward or unfavorable medical occurrences associated with any intervention included in a clinical trial (not just the use of the FDA-regulated product), including any intervention(s) in any arm of the clinical trial that does not involve FDA-regulated products. In addition, as with our proposed definition of adverse event, our proposed definition of serious adverse event encompasses both anticipated and unanticipated effects regardless of attribution or association with the intervention.

Sponsor is a term used in section 402(j) of the PHS Act to define responsible party. Section 402(j)(1)(A)(ix)(I) of the PHS Act explicitly defines ''sponsor'' as such term is defined at 21 CFR 50.3 or any successor regulation. There are two types of sponsors defined in 21 CFR 50.3, both of which meet the definition of sponsor for purposes of this proposed rule. The first type is a ''sponsor,'' which is defined as ''a person who initiates a clinical investigation but who does not actually conduct the investigation, i.e., the test article is administered or dispensed to or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., corporation or agency) that uses one or more of its own employees to conduct a clinical investigation it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators.'' The second is a ''sponsor-investigator,'' which is defined as ''an individual who both

initiates and actually conducts, alone or with others, a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, e.g., corporation or agency.'' We believe that the definition of sponsor used in this proposed rule, must encompass both a sponsor and a sponsor-investigator because both terms are relevant in determining who initiates the clinical trial. Hence, we propose to define sponsor as ''either a 'sponsor' or 'sponsor-investigator', as each is defined 21 CFR 50.3 or any successor regulation.'' Procedures for determining which individual or entity would be considered the sponsor of a applicable clinical trial or other clinical trial subject to this part are specified in proposed § 11.4(c) and described in section IV.A.2 of this preamble. As those sections explain, the individual or entity that is the sponsor will be considered to be the responsible party of an applicable clinical trial or other clinical trial, unless and until that responsibility is delegated to the PI, consistent with the requirements of section 402(j)(1)(A)(ix) of the PHS and this proposed part.

Proposed § 11.10(b) defines certain data elements that are part of the clinical trial information that must be submitted to ClinicalTrials.gov under this proposed part.

B. Registration—Subpart B

Proposed subpart B sets forth the requirements for registration. It identifies who must submit clinical trial registration information; which applicable clinical trials must be registered in ClinicalTrials.gov; when clinical trial registration information must be submitted; where clinical trial registration information must be submitted; what constitutes clinical trial registration information; and by when NIH will post submitted clinical trial registration information.

1. Who must submit clinical trial registration information?—§ 11.20

Proposed § 11.20 requires that ''[t]he responsible party for an applicable clinical trial specified in § 11.22 must register the applicable clinical trial [. . .] .'' This approach is consistent with section 402(j)(2)(C) of the PHS Act, which states that the ''responsible party for an applicable clinical trial . . . shall submit to the Director of NIH for inclusion in the registry data bank the [clinical trial registration information].''

2. Which applicable clinical trials must be registered?—§ 11.22

(a) General specification. Proposed §§ 11.22(a)(1) and (2) specify which applicable clinical trials must be registered with ClinicalTrials.gov. They state that registration is required for: (1) ''[a]ny applicable clinical trial that is initiated after September 27, 2007;'' and (2) [a]ny applicable clinical trial that is initiated on or before September 27, 2007 and is ongoing on December 26, 2007 [. . .] .'' This is consistent with section 402(j)(2)(C) of the PHS Act. We note that under section 402(j)(2)(C)(iii) of the PHS Act, in the case of an applicable clinical trial for a non-serious or non-life-threatening disease or condition that was ongoing as of September 27, 2007, clinical trial registration information was not required to be submitted until September 27, 2008. However, this distinction is no longer relevant because any such trial already should have been registered in the data bank.

We note that this proposal differs from guidance that the Agency originally provided regarding its interpretation of section 402(j)(2)(C) of the PHS Act. The original interpretation may have resulted in some responsible parties registering applicable clinical trials that we no longer believe are subject to the registration requirement of section 402(j)(2)(C) of the PHS Act and this proposed part (i.e., applicable clinical trials for non-serious or non-life-threatening diseases or conditions that were ongoing as of September 27, 2007, but not as of December 26, 2007). We believe that our revised, proposed interpretation more accurately implements the text of section 402(j)(2)(C) of the PHS Act. This revised interpretation was announced to the public in October 2009 through the NIH Guide [Ref. 43], the ClinicalTrials.gov Listserv [Ref. 44], and ClinicalTrials.gov. Although there is no legal requirement for responsible parties to keep clinical trial information for such previously-registered applicable clinical trials in ClinicalTrials.gov, we anticipate that many responsible parties will want to continue to make clinical trial information for such applicable clinical trials available to the public through the data bank. We do not intend to remove these clinical trial records from ClinicalTrials.gov, but we note that the clinical trial information for such clinical trials would be considered voluntary submissions of clinical trial information under section 402(j)(4)(A) of the PHS Act and would be subject to all of the requirements applicable to voluntarily-submitted clinical trial information under section 402(j)(4)(A) of the PHS Act, including but not limited to the requirements that such information be truthful and not misleading in accordance with proposed § 11.6 and updated in accordance with proposed § 11.64. The Agency recognizes that some responsible parties for applicable clinical trials described in this paragraph may not want to be subject to the requirements that apply to clinical trial information submitted under 402(j)(4)(A) of the PHS Act or proposed § 11.60. To address this situation, any responsible party who wishes to remove an active clinical trial record from ClinicalTrials.gov for such an applicable clinical trial must submit an electronic request to the Agency at *register@clinicaltrials.gov* to have the record removed from the data bank. We note that if the Agency removes a clinical trial record from ClinicalTrials.gov as a result of such a request, the clinical trial record would continue to be available to the public in the ClinicalTrials.gov archives; however, the responsible party for such an applicable clinical trial would not be subject to the requirements of section 402(j) of the PHS Act or this proposed part. For example, clinical trial results information is not required to be submitted for these clinical trials.

Proposed § 11.22(a)(3) provides clarification for determining the date on which an applicable clinical trial is initiated. This date is important for determining if an applicable clinical trial is required to register in ClinicalTrials.gov, because, as described above, the registration requirements of section 402(j) of the PHS Act and this proposed part apply only to applicable clinical trials initiated after September 27, 2007, and to applicable clinical trials that were initiated prior to September 27, 2007 and ongoing on December 26, 2007. However, section 402(j) of the PHS Act does not define how to determine when an applicable clinical trial is ''initiated.'' We considered several possibilities for determining the date of initiation, including our longstanding practice for ClinicalTrials.gov which was to consider the date of initiation to be the date that an applicable clinical trial is open to recruitment. In order to be consistent with the definitions of ''ongoing'' and ''enrolled'' and these proposed regulations, we propose instead that for any applicable clinical trial, other than a pediatric postmarket surveillance of a device that is not a clinical trial, the date of initiation means the date on which the first human subject is enrolled in the clinical

trial. For any pediatric postmarket surveillance of a device that is not a clinical trial, we propose that the date of initiation be the date on which FDA approves the plan for conducting the surveillance. This date will be well-documented in correspondence with FDA and represents the first date on which the pediatric postmarket surveillance of a device could be started in accordance with an approved plan.

(b) Determination of applicable clinical trial. Proposed § 11.22(b) sets forth an approach for determining whether or not a clinical trial or study meets the definition of an applicable clinical trial. By relying on certain aspects of the detailed discussions in section IV.A.5 regarding the definitions of applicable device clinical trial and applicable drug clinical trial, this approach outlines specific data elements that would be submitted as part of the registration process. For clinical trials and studies that are registered with ClinicalTrials.gov, it would provide a simple mechanism for determining whether or not the clinical trial or study is an applicable clinical trial that is subject to section 402(j) of the PHS Act and this part, and we could indicate such status in ClinicalTrials.gov. The order in which the data elements are considered would not influence the outcome: A clinical trial for which the submitted information meets the criteria specified below would be considered an applicable clinical trial.

Other than situations where a clinical trial that is not an applicable clinical trial is registered voluntarily (see proposed § 11.60), there is no requirement under section 402(j) of the PHS Act or this proposed part for a responsible party to submit clinical trial registration information to ClinicalTrials.gov for a clinical trial or study that does not meet the definition of an applicable clinical trial. Algorithms following the approach outlined here could be developed to allow potential registrants to determine a priori whether their clinical trial or study meets the definition of an applicable clinical trial, without having to go through the registration process. To this end, we would make such algorithms accessible on ClinicalTrials.gov outside of the registration system.

The proposed approach of using specified data elements to determine whether a clinical trial or study meets the definition of an applicable clinical trial is intended to amend and replace the approach currently implemented in ClinicalTrials.gov, which asks potential registrants to indicate whether their trial is an applicable clinical trial. We believe our proposed approach accurately reflects the proposed definitions of the terms applicable device clinical trial and applicable drug clinical trial. We invite public comment on this proposed approach and on whether there are any types of clinical trials or studies which might be errantly classified as applicable clinical trials that do not in fact meet the definitions of applicable device clinical trial or applicable drug clinical trial, or, conversely, any types of clinical trials or studies that do in fact meet the definitions of applicable device clinical trial or applicable drug clinical trial that might fail to be classified as applicable clinical trials.

Consistent with the elaboration provided in section IV.A.5 of this preamble for the proposed definition of applicable device clinical trial, under proposed § 11.22(b)(1), a study would meet the definition of an applicable device clinical trial if (1) it is a Pediatric Postmarket Surveillance of a Device required by FDA under section 522 of the FD&C Act (regardless of whether the pediatric postmarket surveillance is a clinical trial), (2) it meets all of the following criteria for the submitted data elements: (a) The Study Type is interventional; (b) the Primary Purpose selected is other than feasibility; (c) either the Number of Arms is two or more, or the Number of Arms is one and Single Arm Controlled is selected; (d) the Intervention Type selected is something other than a combination product; (e) the clinical trial Studies an FDA-regulated Device; and (f) one or more of the following applies: At least one Facility Location is within the U.S. or one of its territories, the device under investigation is a Product Manufactured in the U.S. or one of its territories and is exported for study in another country, or the clinical trial has a U.S. Food and Drug Administration IDE Number.

Taking a similar approach for applicable drug clinical trials, and consistent with the elaboration provided in section IV.A.5 of this preamble for the proposed definition of applicable drug clinical trial, proposed § 11.22(b)(2) states that a clinical trial meets the definition of an applicable drug clinical trial if it meets all of the following criteria for the submitted data elements: (1) The Study Type is interventional; (2) the Study Phase is other than phase 1; (3) either the Number of Arms is two or more, or the Number of Arms is one and Single Arm Controlled is selected; (4) the clinical trial Studies an FDA-regulated Drug; and (5) one or more of the following applies: At least one Facility Location is within the U.S. or one of its territories, the drug under investigation is a Product Manufactured in the U.S. and is exported for study in another country, or the clinical trial has a U.S. Food and Drug Administration IND Number.

With respect to Study Phase, we do not consider a phase 1/phase 2 study to be a phase 1 study; therefore, a clinical trial that is indicated to be phase 1/phase 2 would be considered an applicable drug clinical trial if it meets the other conditions listed in (1) through (5) above and would be required to register at ClinicalTrials.gov if it also meets the conditions specified in proposed § 11.22(a). If a clinical trial is registered as phase 1/phase 2, and the trial subsequently proceeds through only the phase 1 stage and/or is terminated before reaching phase 2, the Study Phase data element may be updated to indicate that the trial is a phase 1 trial, in which case it would not be considered an applicable drug clinical trial and would not be subject to the requirements for results submission specified in subpart C. However, submitted registration information would continue to be posted in ClinicalTrials.gov.

While most applicable clinical trials will meet the definition of either an applicable device clinical trial or an applicable drug clinical trial, some applicable clinical trials that study multiple intervention types (e.g., in different arms of the clinical trial) could meet both definitions. For example, a clinical trial with facility locations in the U.S. that studies an FDA-regulated drug in one arm and studies an FDA-regulated device in another arm and compares outcomes of the two arms would meet both definitions. If the device studied in such an applicable clinical trial is not approved or cleared by FDA for any use and is not a component of a combination product, it would be treated as an applicable device clinical trial in that we would not post clinical trial registration information for that clinical trial prior to the date of approval or clearance of the device, consistent with proposed § 11.35(b)(2). We consider this situation to differ from that of an applicable clinical trial in which a studied device is part of a combination product. As explained in the discussion of the definition of an applicable drug clinical trial in section IV.A.5 of this preamble, any applicable clinical trial that studies a combination product would be treated as an applicable drug clinical trial under this proposed rule.

3. When must clinical trial registration information be submitted?—§ 11.24

Proposed § 11.24 specifies the deadlines by which a responsible party must submit clinical trial registration information to register an applicable clinical trial in ClinicalTrials.gov. Consistent with section 402(j)(2)(C) of the PHS Act, proposed § 11.24(a) requires that clinical trial registration information be submitted on the later of December 26, 2007, or 21 calendar days after the first human subject is enrolled in the clinical trial. However, section 402(j)(2)(C)(iii) of the PHS Act provides an exception to this deadline. For any applicable clinical trial that was not for a serious or life-threatening disease or condition (e.g., was not for indications such as acquired immunodeficiency syndrome (AIDS), all other stages of human immunodeficiency virus (HIV), Alzheimer disease, cancer, or heart failure; See [Ref. 4]), was initiated on or before September 27, 2007, and was still ongoing on December 26, 2007, the responsible party must submit clinical trial registration information by the later of September 27, 2008, or 21 calendar days after the first human subject is enrolled in the clinical trial. This proposed rule mirrors this standard in § 11.24(b)(1).

With regard to registering a pediatric postmarket surveillance of a device that is not a clinical trial, the submission deadlines described above may not be applicable because such surveillances may not entail formal recruitment of human subjects. We propose in § 11.24(b)(2), therefore, that registrations of pediatric postmarket surveillances of a device that are not clinical trials be submitted ''not later than December 26, 2007, or 21 calendar days after FDA approves the postmarket surveillance plan, whichever date is later.'' This provides a clear deadline for submission of clinical trial registration information, and the 21-day period is consistent with the requirement in section 402(j)(2)(C)(ii) of the PHS Act that clinical trials be registered 21 days after enrollment of the first human subject.

4. What constitutes clinical trial registration information?—§ 11.28

Proposed § 11.28 identifies the structured information, or data elements, that constitute clinical trial information that a responsible party must submit in order to register an applicable clinical trial. Section 402(j)(2)(A)(ii) of the PHS Act specifies a number of data elements that must be submitted to ClinicalTrials.gov for registration. In general, the proposed data elements in § 11.28 conform to the items enumerated in section 402(j)(2)(A)(ii) of the PHS Act. In many instances, the Agency, through this proposed rulemaking has restated or clarified the registration data elements required by section 402(j)(2)(A)(ii) of the PHS Act. In addition, section 402(j)(2)(A)(iii) of the PHS Act expressly authorizes the Secretary to modify the registration data elements, by regulation, if a rationale is provided as to why such a modification ''improves and does not reduce'' such information. In developing the proposed set of data elements for registration, we carefully considered the items enumerated in section 402(j)(2)(A)(ii) of the PHS Act, the mandate in section 402(j)(2)(A)(i) to ''expand'' the existing registration data bank, and the intent to expand the data bank ''to enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials.'' (*See* section 402(j)(2)(A)(i) of the PHS Act). We have also taken into consideration the WHO trial registration standards and have sought to maintain consistency with the clinical trial registration requirements of the ICMJE [Ref. 13, 10].

Careful consideration was given to the data elements that were part of the data bank prior to passage in 2007 of section 402(j) of the PHS Act, some of which are not expressly required under section 402(j)(2)(A)(ii) of the PHS Act, but which we consider necessary to fulfill both the purpose of the expansion of registration information contained in ClinicalTrials.gov and certain other requirements of section 402(j) of the PHS Act. We believe, in general, that maintaining consistency with the pre-existing data elements for ClinicalTrials.gov is consistent with the intent of section 402(j) of the PHS Act. Not only do we presume that Congress was familiar with those existing definitions when it developed and passed section 402(j) of the PHS Act, but also we believe that maintaining consistency will minimize confusion for those who submitted registration information previously to ClinicalTrials.gov prior to enactment of section 402(j) of the PHS Act. It will also minimize the level of effort required by those who previously established automated computer-based processes for submitting and updating registration data in ClinicalTrials.gov, rather than entering the data manually into the data bank. It will serve the public by facilitating cross-comparison of entries made before and after enactment of section 402(j) of the PHS Act. It also will ensure that the proposed clinical trial registration information requirements would not have the effect of reducing the amount of information available for newly-registered clinical trials as compared to those registered prior to the passage in 2007 of section 402(j) of the PHS Act, a result that we believe would be contrary to the intent of section 402(j) of the PHS Act. For these reasons, we believe that requiring the submission of data elements that were expected to be submitted to ClinicalTrials.gov prior to the passage in 2007 of section 402(j) of the PHS Act in order to register a clinical trial would improve and not reduce the clinical trial information submitted to ClinicalTrials.gov.

As further discussed in section III.C.2 of this preamble, in developing our proposed set of data elements for clinical trial registration information, we have decided to exercise our authority under section 402(j)(2)(A)(iii) of the PHS Act to modify the section 402(j)(2)(A)(ii) requirements for registration information in order to achieve the following objectives:

(1) Specify a particular structure for submitting certain clinical trial registration information in order to: (a) Help the public use the data bank more easily and be able to compare entries, consistent with section 402(j)(2)(B)(iv) of the PHS Act; (b) enable searching of the data bank using criteria listed in sections 402(j)(2)(B)(i) and (ii) of the PHS Act; and (c) facilitate the submission of complete and accurate information by responsible parties;

(2) Enable effective implementation of, or compliance with, other provisions of section 402(j) of the PHS Act and this part, e.g., proposing to add data elements to indicate whether a product under study in a clinical trial in manufactured in the U.S. and whether a study is a pediatric postmarket surveillance of a device, both of which are important to help determine whether a study meets the definition of an applicable clinical trial;

(3) Improve the quality and consistency of clinical trial registration information, e.g., proposing to add Other Intervention Name(s) and Intervention Description to help users identify and differentiate among similar interventions studied in registered clinical trials; or

(4) Demonstrate whether clinical trials registered in the data bank have complied with ethical and scientific review procedures in accordance with applicable statutes and regulations, e.g., proposing to add Human Subjects Protection Review Board Status to indicate to potential human subjects and other users whether an applicable clinical trial has received needed

approvals or is not subject to such requirements.

(a) Registration data elements for applicable clinical trials other than pediatric postmarket surveillances of a device that are not clinical trials. Proposed § 11.28(a) specifies the data elements that a responsible party would be required to submit to ClinicalTrials.gov to register an applicable clinical trial other than a pediatric postmarket surveillance of a device that is not a clinical trial. A pediatric postmarket surveillance of a device that does not take the form of a clinical trial would be registered by submitting the clinical trial information specified in § 11.28(b). The clinical trial registration information data elements in § 11.28(a) are grouped into the four categories used in section 402(j)(2)(A)(ii) of the PHS Act: (1) Descriptive information, (2) recruitment information, (3) location and contact information, and (4) administrative data. Additional data elements that the Agency proposes via this rule are listed in the categories in which they best fit. The clinical trial registration information data elements, grouped by category, are as follows.

(1) Descriptive Information

Brief Title. Section 402(j)(2)(A)(ii)(I)(aa) of the PHS Act specifically requires the submission of a brief title as part of the clinical trial information submitted at registration, but does not define the term, other than to indicate that the title is ''intended for the lay public.'' We interpret this requirement to mean that potential human subjects should be able to understand, from the brief title, the general purpose of the clinical trial and distinguish it from others listed in the data bank. Prior to FDAAA, those submitting information to the ClinicalTrials.gov registry pursuant to FDAMA, were requested to include a ''brief title'' of the trial [Ref. 2]. This term was defined to mean a ''protocol title intended for the lay public'' [Ref. 2]. This definition of ''brief title'' also is consistent with ''public title'' (data item #9) of the WHO Trial Registration standard and ICMJE registration policies [Ref. 13, 10].

Based on our experience to date with ClinicalTrials.gov, we recognize that acronyms are frequently used to refer to clinical trials (e.g., ''ACCORD'' for the Action to Control Cardiovascular Risk in Diabetes trial or ''STAR*D'' for the Sequenced Treatment Alternatives to Relieve Depression trial), and believe it is important for such acronyms to be included in the registry to enable users of the data bank to identify clinical trials that they might see referenced in other media (e.g., news reports, journal articles). As such, we consider an acronym used to identify a clinical trial to be part of the brief title. Therefore, in proposed § 11.10(b)(1), Brief Title is described as ''a short title of the clinical trial written in language intended for the lay public, including any acronym or abbreviation used publicly to identify the clinical trial.'' Although we do not specify what type of information must be conveyed by the Brief Title, we believe that a Brief Title intended for the lay public should include, where possible, information on the participants, condition being evaluated, and intervention(s) studied.

Official Title. Using the authority in section 402(j)(2)(A)(iii) of the PHS Act we propose to require a responsible party to submit an ''official title'' as part of clinical trial information when registering an applicable clinical trial at ClinicalTrials.gov. In proposed § 11.10(b)(2), we define Official Title as: ''The title of the clinical trial, corresponding to the title of the protocol.'' We believe that the official title will complement the Brief Title that is intended for the lay public, by providing a technical title that will help researchers understand the general purpose of the study. The official title would also be helpful in associating the clinical trial in ClinicalTrials.gov with information about the clinical trial that is contained in other sources, such as scientific publications, regulatory submissions, and media reports, which often use the official title of the study protocol. Those who learn about a clinical trial from one of these other sources could more easily search for the trial in ClinicalTrials.gov using the Official Title. Prior to passage of FDAAA, those submitting information to ClinicalTrials.gov were able to submit an ''official title'' as an optional data element, defined to mean ''Official name of the protocol provided by the study principal investigator or sponsor'' [Ref. 2]. This submission of an official title is also consistent with the WHO Trial Registration standard and ICMJE registration policies, which require the submission of a ''scientific title'' (data item #10) [Ref. 13, 10].

Brief Summary. Section 402(j)(2)(A)(ii)(I)(bb) of the PHS Act expressly requires a ''brief summary'' to be submitted as clinical trial registration information, but it does not define the term other than to indicate that the brief summary is ''intended for the lay public.'' Prior to FDAAA, those submitting information to the ClinicalTrials.gov registry pursuant to FDAMA were requested to include a ''brief summary'' of the clinical trial [Ref. 4]. This term was defined to mean a ''short description of the protocol intended for the lay public, including a brief statement of the study hypothesis'' [Ref. 2]. We propose to continue to use that definition. Accordingly, in proposed § 11.10(b)(3), Brief Summary is described as ''a short description of the clinical trial, including a brief statement of the clinical trial's hypothesis, written in language intended for the lay public.''

Primary Purpose. Section 402(j)(2)(A)(ii)(I)(cc) of the PHS Act expressly requires the ''primary purpose'' of the intervention(s) to be submitted as clinical trial registration information, but it does not define the term. Prior to passage of section 402(j) of the PHS Act in 2007, those submitting information to the registry were requested to indicate the primary purpose of the clinical trial. This term was defined to mean the ''reason for the protocol'' [Ref. 2], and those submitting information were given a choice of selections, including ''treatment,'' ''prevention,'' ''diagnostic,'' ''supportive care,'' ''screening,'' ''health services research,'' and ''basic science.'' Data submitters could also indicate ''other'' and include a description of the purpose in the detailed description portion of the clinical trial record. We found this approach effective for indicating the primary purpose of the intervention(s) studied in the clinical trials registered with ClinicalTrials.gov and believe this approach would apply well to clinical trials being registered pursuant to this proposed part. Therefore, under proposed § 11.10(b)(4), Primary Purpose refers to ''the main objective of the intervention(s) being evaluated by the clinical trial.'' We would require a responsible party to provide a response selected from the following set of options: ''treatment'' (for a protocol designed to evaluate one or more interventions for treating a disease, syndrome or condition), ''prevention'' (for a protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition), ''diagnostic'' (for a protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition), ''supportive care'' (for a protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects or mitigate against a decline in the subject's health or function), ''screening'' (for a protocol designed to assess or examine methods of identifying a condition, or risk factors

for a condition, in people who are not yet known to have the condition or risk factor), ''health services research'' (for a protocol designed to evaluate the delivery, processes, management, organization or financing of health care), ''basic science'' (for a protocol designed to examine the basic mechanism of action, e.g., physiology or biomechanics, of an intervention), ''feasibility'' (for a protocol designed to determine the feasibility of a device or test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes), or ''other''. The inclusion of ''feasibility'' on the list of options is intended to permit the responsible party for a clinical trial of a device to indicate whether such clinical trial is a feasibility study. Feasibility studies do not meet the definition of an applicable device clinical trial as specified in section 402(j)(1)(A)(ii) of the PHS Act and § 11.10(a) of this proposed part. A responsible party may nevertheless voluntarily register a clinical trial that is a feasibility study of a device. Such registration would be a voluntary submission of clinical trial information under section 402(j)(4)(A) of the PHS Act and proposed § 11.60.

Study Design. Section 402(j)(2)(A)(ii)(I)(dd) of the PHS Act expressly requires ''study design'' to be submitted as part of clinical trial registration information, but does not define the term. There are many important aspects of a study design, and information about each is relevant to ensuring that the descriptions of study designs are complete and comparable across clinical trials. Hence, we propose to require that several components of study design be submitted. Prior to FDAAA, those submitting information to ClinicalTrials.gov pursuant to FDAMA were requested to include the interventional study characteristics of the trial [Ref. 4]. This term was defined to mean the ''[p]rimary investigative techniques used in the protocol,'' and data submitters were instructed to provide information describing several key attributes of the study design, including the study model, number of arms, masking, and allocation [Ref. 2]. This definition of study design, including the key attributes, conforms to ICH Guidelines [Ref. 23] and is consistent with ''study type'' (data item #15) of the WHO Trial Registration standard (version 1.0) and ICMJE registration policies [Ref. 13, 10]. Consistent with this approach, proposed § 11.10(b)(5) requires that Study Design include information about several important aspects of a clinical trial: interventional study model, number of arms, arm information, allocation, masking, and whether a single-armed clinical trial is controlled. None of these terms is used in section 402(j) of the PHS Act, but we believe each is key component of study design. We propose the following meanings for these terms.

(a) *Interventional Study Model* characterizes the approach used for assigning groups of human subjects to interventions during the clinical trial. In proposed § 11.10(b)(5)(i), the data item is defined as ''[t]he strategy for assigning interventions to human subjects.'' In ClinicalTrials.gov, responsible parties would be required to select an entry from the following limited set of proposed options: ''single group'' (i.e., clinical trials with a single arm), ''parallel'' (i.e., participants are assigned to one of two or more groups in parallel for the duration of the study), ''cross-over'' (i.e., participants receive one of two alternative interventions during the initial phase of the study and receive the other intervention during the second phase of the study), or ''factorial'' (i.e., two or more interventions, each alone and in combination, are evaluated in parallel against a control group). No ''other'' option is proposed. To address those situations in which a clinical trial might use a modified version of one of these models or the responsible party might wish to provide more information about the specific implementation of the model, responsible parties would also be able to provide voluntarily additional free-text description containing more specific details about the interventional study model. We invite public comment on whether the proposed set of options adequately addresses existing and emerging interventional study models, including dose escalation study designs, and whether it would provide suitable selections, without an ''other'' option for all types of applicable clinical trials and voluntarily registered trials that are subject to this proposed regulation.

(b) *Number of Arms* specifies the total number of arms in a clinical trial. We define the term ''arm'' in proposed § 11.10(a). Some clinical trials contain multiple periods or phases, each of which might use different numbers of arms. Hence, in proposed § 11.10(b)(5)(ii), the data element is defined as ''[t]he number of arms in the clinical trial. For a trial with multiple periods or phases that have different numbers of arms, the maximum number of arms during any period or phase.'' We note that historical controls are not considered to be an ''arm'' of a clinical trial and thus are not counted in the number of arms.

(c) *Arm Information* provides key information about each arm in the clinical trial. In proposed § 11.10(b)(5)(iii), the data element is defined as ''[a] description of each arm of the clinical trial that indicates its role in the clinical trial, provides an informative title, and, if necessary, additional descriptive information to differentiate each arm from other arms in the clinical trial.'' Responsible parties would be required to select from the following list of options for describing the role of each arm in the clinical trial: ''experimental,'' ''active comparator,'' ''placebo comparator,'' ''sham comparator,'' ''no intervention,'' or ''other.'' The informative title would consist of a label or short name to identify the arm in the clinical trial record (e.g., the name of the experimental intervention used in the arm or placebo). Additional descriptive information would be required if the informative title does not sufficiently differentiate among arms in the clinical trial (e.g., in a clinical trial that compares two different dosages of the same investigational drug, the descriptive information would have to indicate which is the higher dose arm versus the lower dose arm). Even if the informative title and/or additional descriptive information vary sufficiently among the arms of the clinical trial, responsible parties may voluntarily include additional details about the interventions or the arms in this field.

(d) *Allocation* describes how human subjects are assigned to interventions. In proposed § 11.10(b)(5)(iv), the data item is defined as ''[t]he method by which human subjects are assigned to arms in a clinical trial.'' Responsible parties would be required to select from the following limited set of options: ''randomized'' (participants are assigned to intervention groups by chance), or ''nonrandomized'' (participants are expressly assigned to intervention groups through a non-random method, such as physician choice), or ''not applicable'' (for a single arm study). No ''other'' option is proposed. We invite public comment on whether this limited set of options would provide suitable selections for all types of applicable clinical trials and voluntarily registered clinical trials that are subject to this proposed rule.

(e) *Masking* specifies which entities, if any, involved in the clinical trial are not informed of the intervention assignments (i.e., who is ''blinded'' in the clinical trial). In proposed § 11.10(b)(5)(v), the data item is defined as ''[t]he party or parties, if any, involved in the clinical trial who are prevented from having knowledge of the interventions assigned to individual human subjects.'' In the data bank,

responsible parties would be required to select from the following limited menu of choices for describing which party(ies) is/are blinded: ''human subject,'' ''care provider,'' ''investigator,'' and/or an ''outcomes assessor'' (i.e., another individual who evaluates the outcome(s) of interest). No ''other'' option is proposed, but responsible parties would have the ability to voluntarily provide additional, free-text, information about other parties who might be blinded in clinical trial.

(f) *Single Arm Controlled*? is not a data element that is explicitly listed in section 402(j) of the PHS Act as part of clinical trial information, but we propose it as a sub-element part of Study Design to enable the Agency to determine whether a registered clinical trial is an applicable clinical trial when such a determination cannot be made based on other submitted registration data elements. This data element, which is described in proposed § 11.10(b)(5)(vi) as ''[f]or a single-armed clinical trial only, whether or not the clinical trial is controlled, as specified by the protocol or statistical analysis plan,'' would assist the Agency, responsible parties, and users of the data bank in determining whether a clinical trial with only one arm meets the definition of an applicable clinical trial. As explained in section IV.A.5 of this preamble, a study of a device that is not a pediatric postmarket surveillance of a device can meet the definition of an applicable device clinical trial only if it ''compar[es] an intervention with a device . . . against a control in human subjects.'' (See 402(j)(1)(A)(ii)(I) of the PHS Act.) Similarly, a clinical trial of a drug can meet the definition of an applicable drug clinical trial only if it is ''a controlled clinical investigation . . .'' (See 402(j)(1)(A)(iii)(I)).

As explained in the definition of the term ''controlled'' in section IV.A.5 of this preamble, we consider any clinical trial with two or more arms to be controlled and/or to compare an intervention against a control. A clinical trial with only one arm (a single-armed study) may or may not be controlled and/or compare an intervention against a control, depending on whether or not the data collected on human subjects in the clinical trial will be compared to non-concurrently collected data. To determine whether a clinical trial with only one arm meets this criterion, we propose to require the responsible party for a single-armed study to indicate whether the clinical trial is controlled, as defined in this part. In doing so, the responsible party would consider whether the protocol or statistical analysis plan for the clinical trial indicates that data collected in the single-arm clinical trial will be compared to non-concurrently collected data, such as an historical control group. To reduce the burden on responsible parties, we would require this element of Study Design to be submitted only if the other clinical trial information submitted by the responsible party indicates that the clinical trial has one arm and otherwise meets the criteria for an applicable clinical trial, as listed in proposed § 11.22(b) (section IV.B.2(b) of this preamble). If other submitted registration data elements demonstrate that the clinical trial is not an applicable clinical trial or that it includes two or more arms, the Single Arm Controlled? data element would not need to be submitted.

Study Phase. Section 402(j)(2)(A)(ii)(I)(ee) of the PHS Act expressly requires, for an applicable drug clinical trial, the ''study phase'' to be submitted as a clinical trial registration information data element, but it does not define the term. Prior to FDAAA, those submitting registration information to ClinicalTrials.gov pursuant to FDAMA were requested to include the study phase of the clinical trial [Ref. 4]. This term was interpreted to mean ''phase of investigation, as defined by FDA for trials involving investigational new drugs'' [Ref. 2]. In proposed § 11.10(b)(6), the data item is defined as ''for a clinical trial of a drug, the numerical phase of such clinical trial, consistent with terminology in 21 CFR 312.21, or any successor regulation, such as phase 2 or phase 3, and in 21 CFR 312.85, or any successor regulation, for phase 4 studies.'' Responsible parties would be required to select one response from a limited list of options that includes phases 1, 2, 3, and 4, consistent with the terminology in 21 CFR 312.21 and 21 CFR 312.85. In addition, they would be able to select from other options that are commonly used in practice: Phase 1/phase 2 (for trials that are a combination of phases 1 and 2; as discussed previously, phase 1/phase 2 studies are not considered phase 1 studies and may be applicable drug clinical trials); and phase 2/phase 3 (for trials that are a combination of phases 2 and 3). No ''other'' option is proposed. Although we are aware that the term ''phase 0'' is used in practice (e.g., to refer to clinical trials that are exploratory in nature and are not designed to evaluate therapeutic or diagnostic intent), any trial that would be referred to as ''phase 0'' meets the definition of a phase 1 trial under FDA's regulations (21 CFR 312.21). Therefore, we do not propose to include ''phase 0'' as an option for the Study Phase data element, and responsible parties registering a clinical trial that might be referred to as ''phase 0'' should indicate the Study Phase as ''phase 1''. Study phases are not intended for use in describing clinical trials of devices, and therefore, consistent with section 402(j)(2)(A)(ii)(I)(ee) of the PHS Act, responsible parties for applicable device clinical trials would not be required to submit this data element.

Study Type. Section 402(j)(2)(A)(ii)(I)(ff) of the PHS Act expressly requires ''study type'' to be submitted as clinical trial information at the time of registration, but it does not define the term. Prior to FDAAA, those submitting information to the registry pursuant to FDAMA were requested to include the study type of the record being submitted to the registry by indicating whether the record corresponded to an interventional study (i.e., a clinical trial), an observational study, or an expanded access program. The study type selected would determine which other data elements to submit [Ref. 4]. Consistent with prior practice, proposed § 11.10(b)(7) defines the Study Type date element as ''the type of study for which clinical trial information is being submitted.'' Responsible parties would be required to select one of the following limited set of options: ''interventional,'' ''observational,'' or ''expanded access program.'' No ''other'' option is proposed. We believe that all applicable clinical trials and all other clinical studies that might be registered voluntarily with ClinicalTrials.gov can be characterized accurately as either ''interventional'' or ''observational,'' depending on whether human subjects studied are assigned to interventions based on a study protocol (interventional) or patients receive interventions as part of routine medical care, and a researcher studies the effect of the intervention (observational). We would consider observational studies to include a wide range of non-interventional studies, including retrospective reviews of patient records or relevant literature. (*See* the elaboration of the terms applicable device clinical trial and applicable drug clinical trial in section IV.A.5 of this preamble). A study that is designated as ''interventional,'' as that term is defined in this proposed part, may or may not be an applicable clinical trial, depending on whether it meets the other criteria for an applicable clinical trial that are specified in this part. A study that is designated ''observational''

would be an applicable clinical trial only if it is a pediatric postmarket surveillance of a device as defined in this part. (*See* the proposed definition of pediatric postmarket surveillance of a device in § 11.10, the discussion of proposed § 11.28(b), and the discussion of observational studies in section IV.A.5 of this preamble). Conversely, any applicable clinical trial other than a pediatric postmarket surveillance of a device must always have a Study Type of ''interventional.'' An applicable clinical trial that is a pediatric postmarket surveillance of a device could have a Study Type of ''interventional'' or ''observational.'' The term, ''expanded access program,'' is proposed as an option for Study Type because responsible parties are required to enter the data elements describing an expanded access program that is not an applicable clinical trial by creating an expanded access record if there is an expanded access program for the drug or biological product under study in the clinical trial being registered, consistent with section 402(j)(2)(A)(ii)(II)(gg) of the PHS Act, and if such a record does not already exist. As discussed in section IV.A.5 of this preamble, we expect that most expanded access programs will not meet the definition of an applicable clinical trial. The appropriate Study Type for expanded access programs that do not meet the definition of applicable clinical trial would be ''expanded access program.'' The appropriate Study Type for an expanded access program that does meet the definition of applicable clinical trial would be ''interventional.'' An expanded access program must be registered under only one Study Type. (See discussion of proposed § 11.28(c)). We invite public comment on our proposal for Study Type, including whether the limited set of options proposed would provide suitable selections for all types of applicable clinical trials and voluntarily registered clinical trials that are subject to this proposed rule.

Whether the Study is a Pediatric Postmarket Surveillance of a Device. We propose, in § 11.28(a)(1)(viii), to add a requirement for responsible parties of a study of a device to indicate if the study is a pediatric postmarket surveillance of a device. As we stated previously, the term ''applicable device clinical trial'' is defined, in part, as ''a pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act.'' (See section 402(j)(1)(A)(ii)(II) of the PHS Act). A responsible party would be required to provide this data element only if the study is a pediatric postmarket surveillance of a device; a responsible party would not be required to submit this data element if the device study is not a pediatric postmarket surveillance of a device.

By indicating that a study is a pediatric postmarket surveillance of a device, users of the data bank and the Agency would be able to confirm that the study is an applicable device clinical trial. In addition, by combining this information with other submitted clinical trial registration information, e.g., the Study Type data element (interventional, observational), the Agency could confirm whether the pediatric postmarket surveillance of a device is a clinical trial and indicate which other data elements must be submitted at the time of registration. If a pediatric postmarket surveillance of a device is a clinical trial, the clinical trial registration information data elements set forth at proposed § 11.28(a) are required to be submitted. If a pediatric postmarket surveillance of a device is not a clinical trial (i.e. it is a form of observational study, including a retrospective review of patient records or relevant literature), the clinical trial registration information data elements set forth in § 11.28(b) are required to be submitted.

Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study. Section 402(j)(2)(A)(ii)(I)(gg) of the PHS Act expressly requires ''the primary disease or condition being studied, or the focus of the study'' to be submitted as part of clinical trial registration information, but it does not define the term. Section 402(j)(2)(B)(i)(I) of the PHS Act further requires the data bank to be searchable by one or more of eight listed criteria, including ''the disease or condition being studied in the clinical trial, using Medical Subject Headers (MeSH) descriptors.'' To support searching using MeSH descriptors, the primary disease or condition being studied in the clinical trial, or the focus of the study, must be described using either MeSH terminology (*http://www.nlm.nih.gov/mesh/*) or another terminology that has been mapped to MeSH, when possible (if the other terminology is mapped to MeSH, the data bank can be searched using MeSH terms and retrieve the correct record(s)). SNOMED CT (Systematized Nomenclature of Medicine—Clinical Terms) (*http://www.ihtsdo.org/snomed-ct/*) meets the criteria of having been mapped to MeSH and has been designated as a U.S. standard for certified electronic health records that meet specified criteria for meaningful use of health information technology. (*See http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf*). Other vocabularies have also been mapped to MeSH within the NLM's Unified Medical Language System® (UMLS®) Metathesaurus. While it is possible that not all primary diseases or conditions or study foci can be expressed using MeSH, SNOMED CT, or another vocabulary that is mapped to MeSH within the UMLS Metathesaurus, we believe such terminology would accommodate most clinical trials and must be used when available. When a suitable term is unavailable in MeSH, SNOMED CT, or another vocabulary that is included in the UMLS Metathesaurus, ClinicalTrials.gov can accept another English language entry that accurately describes the primary disease or condition being studied, or the focus of the study. ClinicalTrials.gov could then use the information to enable searching by MeSH terms. Therefore, under proposed § 11.10(b)(9), we define Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study as ''the name(s) of the disease(s) or condition(s) studied in the clinical trial, or the focus of the clinical trial, using, if available, appropriate descriptors from the National Library of Medicine's Medical Subject Headings (MeSH) controlled vocabulary thesaurus *http://www.nlm.nih.gov/mesh/,* or terms from another vocabulary, such as the Systematized Nomenclature of Medicine—Clinical Terms (SNOMED CT), that has been mapped to MeSH within the Unified Medical Language System (UMLS) Metathesaurus (*https://uts.nlm.nih.gov*).'' This definition is consistent with ''health condition(s) or problem(s) studied'' (data item #12) of the WHO Trial Registration standard (version 1.0) and ICMJE registration policies [Ref. 13, 10]. It is also consistent with the terminology used in ClinicalTrials.gov prior to FDAAA when those submitting information to the registry in response to FDAMA were requested to include ''conditions or focus of study,'' which were described as the ''primary disease or condition being studied, or focus of the study,'' and submitters were directed to describe the diseases or conditions using MeSH controlled vocabulary when possible [Ref. 2, 4].

Intervention Name(s). Section 402(j)(2)(A)(ii)(I)(hh) of the PHS Act expressly requires ''intervention name'' to be submitted as part of clinical trial information at the time of registration, but it does not define the term. We believe the purpose of this data element is to enable interested parties to readily identify the intervention(s) being studied in each arm of a clinical trial

and compare clinical trials by intervention. While some clinical trials compare a single intervention against a placebo (which would not need to be listed as a separate intervention), many compare multiple interventions (e.g., a new drug versus standard treatment, or different dosages of the same drug). We believe it is important for the names of all interventions studied in a clinical trial to be submitted to the data bank. Based on our previous experience in operating ClinicalTrials.gov, we recognize that there are inherent difficulties in determining the level of detail that should be required for naming interventions, especially those without non-proprietary (i.e., generic) names [Ref. 4]. We believe that non-proprietary names must be provided for interventions (e.g., drugs, biological products, and devices) when available. For interventions for which a non-proprietary name is not available, our prior experience suggests that a brief descriptive name can suffice. In either case, additional descriptive information is often needed to distinguish the intervention(s) under study from other similar interventions used in practice or studied in the same or other clinical trials. Therefore, under proposed § 11.10(b)(10), Intervention Name(s) is specified as ''a brief descriptive name used to refer to the intervention(s) studied in each arm of the clinical trial. A non-proprietary name of the intervention must be used, if available. If a non-proprietary name is not available, a brief descriptive name or identifier must be used.'' Examples of a brief descriptive name or identifier include a chemical name, company code or serial number. This description of Intervention Name is consistent with the ''intervention(s)'' (data item #13) of the WHO Trial Registration standard (version 1.0) and ICMJE registration policies [Ref. 13, 10]. It is also consistent with use of the term in ClinicalTrials.gov prior to FDAAA when those submitting information to the ClinicalTrials.gov registry pursuant to FDAMA were requested to include the intervention name for each intervention involved in the trial [Ref. 4], and the term was defined to mean the ''generic name of the precise intervention being studied. For investigational new drugs that do not yet have a generic name, a chemical name, company code or serial number may be used on a temporary basis.'' Our current proposal is consistent with this approach.

Other Intervention Name(s) is a term that is not used in section 402(j) of the PHS Act, but is proposed as a data element that responsible parties must submit if the sponsor has used more than one name publicly to identify the intervention under study in a clinical trial. Based on our prior experience operating ClinicalTrials.gov, we are aware that interventions often have multiple names, including, for example, a sponsor code name, brand name(s), or a name or identifier from a standard vocabulary, such as RxNorm for drugs (*http://www.nlm.nih.gov/research/umls/rxnorm/index.html*). Accordingly, providing only a single name for each intervention (as is required under the Intervention Name(s) data element) does not necessarily provide enough information to allow users to find and compare all clinical trials in ClinicalTrials.gov that involve a specific intervention, as a different clinical trial with the same intervention may have been registered by another responsible party under a different intervention name. Therefore, we believe that adding a requirement to submit Other Intervention Name(s) improves and does not reduce the clinical trial information available in the data bank. Under proposed § 11.10(b)(11), this term is defined as ''other current and former name(s) or alias(es), if any, different from the Intervention Name(s), that the sponsor has used publicly to identify the intervention, including, but not limited to, past or present names such as brand name(s), serial numbers, or chemical descriptions.'' This requirement could mean that, in some circumstances (e.g., when the responsible party is a designated principal investigator), the responsible party would need to communicate with the sponsor or the manufacturer of the intervention(s) to determine whether another name has been used publicly. We do not believe such additional communication would be frequent or onerous. This proposal would not require a responsible party to submit names that have not been used publicly because users of ClinicalTrials.gov would be unlikely to search for a clinical trial using such names. We seek comment on this approach.

Intervention Description. The term ''intervention description'' is not used in section 402(j) of the PHS Act, but we propose it as an additional data element to be submitted as clinical trial information at the time of registration. Based on prior experience, we recognize that the Intervention Name(s) and Other Intervention Name(s) data elements, whether providing information on brand or non-proprietary names, do not always provide enough information to allow potential human subjects or other users to differentiate among similar interventions used in different arms of a clinical trial, or to distinguish the intervention used in one clinical trial from a similar intervention used in another clinical trial, or to understand the differences between interventions studied in a clinical trial and those used in routine medical practice. For example, a clinical trial might compare two or more dosages of the same drug or two different clinical trials might examine drug-eluting stents that are similar to those used in standard medical practice. To reduce this ambiguity, additional descriptive information is needed about the intervention, such as information about the dosage, dosage form, frequency of administration, route of administration, and/or duration of administration of a drug, or a general description of the device, including how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as its key components and general types of materials used. The submission of such information will enable users (whether subjects, patients, physicians, researchers, or others) to understand key elements of a clinical trial, and compare information among clinical trials. For these reasons, requiring submission of an Intervention Description would improve but not reduce the clinical trial information available in the data bank. Under proposed § 11.10(b)(12), the term is defined to mean ''details that can be made public about the intervention, other than the Intervention Name and Other Intervention Name(s), sufficient to distinguish it from other, similar interventions studied in the same or another clinical trial.'' The information should be sufficiently detailed to differentiate the specified intervention from other similar interventions, but should not include information that the responsible party cannot make public. For example, if the specific dosage of a drug being studied cannot be divulged, a responsible party could instead indicate if the dosage is higher or lower than that used in an approved or licensed drug or in another arm of the study. If an experimental device uses different material than previous versions of the device, or than other marketed devices, the responsible party could provide a general description of the new material without including its specific formulation.

Intervention Type. Section 402(j)(2)(A)(ii)(I)(hh) of the PHS Act expressly requires ''intervention type'' to be submitted as part of clinical trial information at the time of registration,

but it does not define the term. Prior to FDAAA, those submitting information to the ClinicalTrials.gov registry were requested to specify the intervention type for each intervention studied in the clinical trial. Under proposed § 11.10(b)(13) Intervention Type would be defined as ''for each intervention studied in the clinical trial, the general type of intervention.'' When submitting this information, responsible parties would be required to select one of the following options for each intervention studied: ''drug'' (including placebo), ''device'' (including sham), ''biological/vaccine,'' ''procedure/surgery,'' ''radiation,'' ''behavioral'' (e.g., psychotherapy, lifestyle counseling), ''genetic'' (including gene transfer, stem cell and recombinant DNA), ''dietary supplement'' (e.g., vitamins, minerals), ''combination product'' (combining a drug and device, a biological product and device; a drug and biological product; or a drug, biological product, and device), ''diagnostic test'' (e.g., imaging in-vitro), and ''other.'' Note that when the intervention used is a combination product (e.g., drug-eluting stent), the responsible party must select ''combination product'' as the Intervention Type. As specified in proposed § 11.28(a)(1)(xiii), selection of an Intervention Type would be required for each intervention studied in each arm of the clinical trial. Some clinical trials will therefore include multiple Intervention Types. As discussed in section IV.B.2(b) of this preamble, a clinical trial that studies a drug and a device as separate, independent interventions would list both ''drug'' and ''device'' as Intervention Types and may meet the definitions of both an applicable device clinical trial and an applicable drug clinical trial.

Studies an FDA-Regulated Device. Section 402(j) of the PHS Act does not explicitly require submission of a clinical trial registration information data element to indicate whether or not a clinical trial studies an FDA-regulated device. We propose to require such a data element using our authority under section 402(j)(2)(A)(iii) of the PHS Act to assist responsible parties, users of ClinicalTrials.gov, and the Agency in determining whether or not a clinical trial is an applicable device clinical trial, using the approach specified in proposed § 11.22(b)(1). As specified in the elaboration of the definition of an applicable device clinical trial in section IV.A.5 of this preamble, one criterion for an applicable device clinical trial is that the clinical trial studies a device ''subject to section 510(k), 515, or 520(m) of the [FD&C Act].'' It is possible that a clinical trial with an Intervention Type of ''device'' would not be an applicable device clinical trial because the device is not subject to section 510(k), 515, or 520(m) of the FD&C Act. Conversely, it is possible that a clinical trial could be an applicable device clinical trial even if none of the specified Intervention Types is ''device.'' For example, a clinical trial for which a responsible party indicates the Intervention Type is ''radiation,'' ''genetic,'' or ''procedure'' could in fact be an applicable device clinical trial studying a device subject to section 510(k), 515, or 520(m) of the FD&C Act (e.g., an x-ray device, a genetic test, or a surgical device). If the responsible party has obtained an IDE and submitted an IDE number to ClinicalTrials.gov, it would be clear that the clinical trial is an applicable device clinical trial as defined in this part (assuming, as discussed previously, that the clinical trial is not a clinical trial of a combination product). If the responsible party does not submit an IDE number, however, ambiguity would arise because the lack of an IDE number (or an IDE) does not per se indicate that a clinical trial is not an applicable device clinical trial.

To avoid this ambiguity and help ensure that applicable clinical trials can be properly identified, we propose to require a responsible party to specifically indicate whether or not a clinical trial studies an FDA-regulated device by submitting the Studies an FDA-regulated Device data element. The data element is defined in proposed § 11.10(b)(39) to mean that ''a clinical trial studies a device that is subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act.'' Consistent with the elaboration of the term applicable device clinical trial in section IV.A.4 of this preamble, we interpret this definition to mean that the clinical trial studies a device that would require any of the following before it may be legally marketed in the U.S.: (1) A finding of substantial equivalence under section 510(k) of the FD&C Act; (2) an order under section 515 of the FD&C Act approving a premarket approval application for the device, or (3) a humanitarian device exemption under section 520(m) of the FD&C Act. We believe that submission of this information would improve and not reduce the clinical trial information submitted at the time of registration by making it clear to the responsible party, the Agency, and users of ClinicalTrials.gov whether or not a clinical trial without an IDE studies an FDA-regulated device. This information would, in turn, be used in determining whether a clinical trial meets the definition of an applicable device clinical trial, following the approach specified in proposed § 11.22(b)(1). To reduce the data entry burden on responsible parties, ClinicalTrials.gov could automatically pre-populate this data field to indicate ''yes'' if a responsible party submits an IDE number as part of the FDA IND or IDE Number data element specified in proposed § 11.10(b)(35).

We are aware that devices may be used in clinical trials even though they are not the intervention studied in the clinical trial or the experimental variable of interest in the study. For example, clinical trials of procedures involving surgical devices may not be designed to study the effect of these devices. Therefore, when considering whether a clinical trial Studies an FDA-regulated Device a responsible party should consider whether: (a) The study is designed to examine the effect or performance of an FDA-regulated device, or differences in the intended use, e.g., variations in frequency of use, method of administration, design specifications, and other characteristics (e.g., used in one or more, but not all, arms in a multi-arm study); and/or (b) at least one pre-specified primary or secondary outcome measure reflects a characteristic, effect, or performance of an FDA-regulated device (e.g., need for replacement or maintenance of the device).

Studies an FDA-Regulated Drug. Section 402(j) of the PHS Act does not explicitly require submission of a clinical trial registration information data element to indicate whether or not a clinical trial studies an FDA-regulated drug. We propose to require such a data element using our authority under section 402(j)(2)(A)(iii) of the PHS Act to assist responsible parties, users of ClinicalTrials.gov, and the Agency in determining whether or not a clinical trial is an applicable drug clinical trial using the approach specified in proposed § 11.22(b)(1). As specified in the elaboration of the definition of an applicable drug clinical trial in section IV.A.5 of this preamble, one criterion for an applicable drug clinical trial is that the clinical trial studies a drug ''subject to section 505 of the [FD&C] Act or [a biological product subject] to section 351 of [the PHS] Act.'' It is possible that a clinical trial with an Intervention Type of ''drug'' or ''biological product'' would not be an applicable drug clinical trial because the drug is not subject to section 505 FD&C Act (e.g., a non-prescription drug that is marketed under an over-the-counter drug monograph)

and/or the biological product is not subject to section 351 of the PHS Act. Conversely, it is possible that a clinical trial could be an applicable drug clinical trial even if none of the specified Intervention Types is ''drug'' or ''biological product.'' A clinical trial for which the responsible party indicates the Intervention Type to be ''dietary supplement'' or ''genetic'' or ''procedure'' could in fact be an applicable drug clinical trial studying a drug subject to section 505 of the FD&C Act or a biological product subject to section 351 of the PHS Act. For example, a dietary supplement could be studied for treatment of cancer, or a genetic trial could study a gene therapy. If the responsible party has obtained an IND and submitted an IND number to ClinicalTrials.gov, then it would be clear (assuming, as discussed previously, that the clinical trial is not a clinical trial of a combination product) that the clinical trial is an applicable drug clinical trial as defined in this part. If the responsible party does not submit an IND number, however, ambiguity would arise because the lack of an IND number (or an IND) does not per se indicate that a trial is not an applicable drug clinical trial. To avoid this ambiguity and help ensure that applicable clinical trials can be properly identified, we propose to require a responsible party to specifically indicate whether or not a clinical trial studies an FDA-regulated drug by submitting the Studies an FDA-regulated Drug data element. The data element is defined in proposed § 11.10(b)(40) to mean that ''a clinical trial studies a drug that is subject to section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act.'' Consistent with the elaboration of the term applicable drug clinical trial in section IV.A.4 of this preamble, we interpret this definition to mean that the clinical trial studies a drug that is the subject of an approved new drug application (NDA) or biologics license application (BLA) or that would require an approved NDA or BLA to be legally marketed in the U.S. We believe that submission of this information would improve and not reduce the clinical trial information submitted at the time of registration by making it clear to the responsible party, the Agency, and users of ClinicalTrials.gov whether or not a clinical trial without an IND studies an FDA-regulated drug or biological product. This information would, in turn, be used in determining whether a clinical trial meets the definition of an applicable drug clinical trial, following the approach specified in proposed § 11.22(b)(2). To reduce the data entry burden on responsible parties, ClinicalTrials.gov could automatically pre-populate this data field to indicate ''yes'' if a responsible party submits an IND number as part of the FDA IND or IDE Number data element specified in proposed § 11.10(b)(35).

We are aware that a clinical trial may include an FDA-regulated drug even though the drug is not a variable of interest. For example, a clinical trial of a device may involve the surgical insertion of the device under anesthesia, but the anesthesia drug is not studied in the clinical trial. In determining whether a clinical trial Studies an FDA-regulated Drug a responsible party should consider whether: (a) The clinical trial is designed to examine the effect of the FDA-regulated drug(s), or of differences in the intended use, including differences in dosing, frequency of use, or route of administration; and/or (b) at least one of the pre-specified primary or secondary outcome measures reflects a characteristic or effect of the FDA-regulated drug(s).

U.S. FDA Approval, Licensure, or Clearance Status. We propose U.S. FDA Approval, Licensure, or Clearance Status to be submitted as clinical trial information to indicate whether any intervention regulated by FDA and studied in the clinical trial has been approved, licensed, or cleared for any use. Such information would help in ensuring that the data bank operates in compliance with statutory requirements. For example, knowledge of the approval or clearance status of a device is necessary to determine when clinical trial registration information submitted for an applicable device clinical trial may be posted publicly in the data bank. (See section 402(j)(2)(D)(ii) of the PHS Act.) This information also would be helpful for users of ClinicalTrials.gov, including potential participants, who might wish to know whether or not the product(s) under study have been approved, licensed, or cleared for the use studied in the clinical trial. Requiring submission of the approval, licensure, or clearance status for each drug or device studied in an applicable clinical trial would therefore improve and not reduce the clinical trial information available in the data bank, consistent with section 402(j)(2)(A)(iii) of the PHS Act for proposed modifications to clinical trial registration information. We propose referring explicitly to the ''U.S.'' FDA to provide clarification for those submitting information about foreign clinical trials to ClinicalTrials.gov. In proposed § 11.10(b)(14), we therefore define U.S. FDA Approval, Licensure, or Clearance Status, to mean, ''for each drug or device studied in the clinical trial, whether that drug or device is approved, licensed, or cleared by the U.S. Food and Drug Administration for any use.'' We would require responsible parties to select a response from the following limited list of choices: ''for studied use(s)'' (the drug, biological product, or device is approved, licensed, or cleared for the use studied in the clinical trial; ''for other use(s)'' (the drug, biological product, or device is approved, licensed, or cleared for use(s) other than those studied in the clinical trial, e.g., the clinical trial studies a new use of the product); ''No'' (the product has not been approved, licensed, or cleared for any use). No ''other'' option is proposed, but a responsible party would also be able to provide voluntarily additional free-text information to further describe the approval, licensure, or clearance status, e.g., to indicate that the product has been approved in another dose or dosage form, or to list the indications for which it has been approved. We invite public comment on whether the set of proposed options is sufficient to describe the approval, licensure, or clearance status of FDA-regulated drugs or devices that would be studied in applicable clinical trials or voluntarily registered clinical trials that are subject to this proposed rule.

Product Manufactured in the U.S. Section 402(j) of the PHS Act does not explicitly require a data element to be submitted as part of clinical trial information to indicate whether a product under study is manufactured in the U.S, but we propose to include it using our authority under section 402(j)(2)(A)(iii) of the PHS Act to allow users to determine whether a registered clinical trial is an applicable clinical trial. This data element, which is defined in § 11.10(b)(15) as ''for a drug or device studied in a clinical trial, whether or not the drug or device is manufactured in the U.S. or one of its territories,'' will assist the Agency in determining whether a clinical trial meets the definition of an applicable clinical trial. As explained above in the definitions of ''applicable device clinical trial'' and ''applicable drug clinical trial,'' even if a clinical trial is being conducted entirely outside of the U.S. or one of its territories, it may be considered an applicable clinical trial where the drug or device is subject to regulation under the FD&C Act. A drug or device is considered to be subject to regulation under the FD&C Act if the product under investigation is

manufactured in the U.S. or one of its territories and is exported for study in another country, either under an IND, pursuant to 21 CFR 312.110, or any successor regulation, or under section 801(e) or 802 of the FD&C Act. Thus, information indicating whether each intervention studied in a clinical trial is manufactured in the U.S. or one of its territories would be essential in some situations to determine whether such trial is subject to FDA jurisdiction and meets the definition of an applicable clinical trial.

To reduce data submission burden, this data element would need to be submitted to ClinicalTrials.gov only if the entry submitted for the U.S. Food and Drug Administration IND or IDE Number data element indicates that there is no IND or IDE for the clinical trial, and the entry(ies) for the Facility Information data element include no facility locations in the U.S. or its territories. In those situations in which a responsible party would be required to submit information about whether the product(s) under study is manufactured in the U.S., including this information in the data bank would improve and not reduce clinical trial information by publicly providing data necessary to determine whether or not such trial is an applicable clinical trial. Accordingly, we propose the addition of this data element as clinical trial registration information pursuant to our authority to modify the requirements for clinical trial registration information under section 402(j)(2)(A)(iii) of the PHS Act.

Study Start Date. Section 402(j)(2)(A)(ii)(I)(ii) of the PHS Act expressly requires ''study start date'' to be submitted as clinical trial information at the time of registration, but it does not define this term. Prior to passage in 2007 of section 402(j) of the PHS Act, those submitting information to ClinicalTrials.gov were requested to include the study start date of the trial, which was defined as the ''date that enrollment to the protocol begins'' [Ref. 2], meaning the date on which the clinical trial is open to enrollment, even if no subjects are enrolled on that date. The WHO Trial Registration standard (version 1.0) and ICMJE registration policies, in contrast, define the term study start date (data item #16) as the ''date of first enrollment'' [Ref. 13, 10].

Section 402(j)(2)(C)(ii) of the PHS Act and proposed § 11.24(a) generally require that clinical trial registration information be submitted to ClinicalTrials.gov not later than 21 calendar days after the first human subject is enrolled in the clinical trial. In practice, however, many responsible parties submit clinical trial registration information to ClinicalTrials.gov before the first subject is enrolled. In some cases, at the time the clinical trial is registered, the responsible party might not have information about when the first subject will be enrolled or when the first subject was enrolled (for example, in a large multi-site trial) but might know only when the clinical trial was or will be opened for enrollment. To account for these potential scenarios, we propose that responsible parties be required to provide an estimated study start date (i.e., the estimated date on which the clinical trial will be open to enrollment of human subjects), unless and until the responsible party knows the actual study start date (i.e., the actual date on which the first human subject is enrolled). Not later than 21 days after the first human subject is enrolled, the responsible party would be required to update the Study Start Date data element to reflect the actual study start date, consistent with proposed § 11.64. Providing the estimated study start date to the public, even before the first subject is enrolled, has important benefits to potential human subjects because it will allow them to know when a clinical trial likely will be open to enrollment. Hence, in proposed § 11.10(b)(16) we define Study Start Date to mean: ''the estimated date on which the clinical trial will be open to enrollment of human subjects. If the clinical trial has enrolled the first human subject, the actual date on which the first human subject was enrolled.'' The Study Start Date must include the day, month, and year. We note that if a clinical trial is registered with an estimated study start date but the clinical trial then is halted before enrolling the first subject (e.g., because of difficulties in recruitment, loss of funding, etc.), the responsible party would not be expected to update the study start date; rather, responsible party would be expected to update the Overall Recruitment Status data element specified in proposed § 11.10(b)(25) to indicate that the clinical trial has been ''withdrawn,'' as such term is used for the purpose of this regulation, and to update the Why Study Stopped data element specified in proposed § 11.10(b)(26).

Completion Date. Section 402(j)(2)(A)(ii)(I)(jj) of the PHS Act requires the responsible party to submit information on the ''expected completion date'' of an applicable clinical trial when registering a clinical trial. The public availability of information about the expected completion date is important for an ongoing clinical trial because it provides an indication of the relative progress of the clinical trial and the expected date on which results information may be submitted to the data bank because section 402(j)(3)(E)(i) of the PHS Act requires that, in general, clinical trial results information be submitted not later than 1 year after the earlier of the estimated completion date of the applicable clinical trial or the actual completion date of the applicable clinical trial. We note, as described in the discussion of proposed § 11.44, that certain exceptions apply to this general deadline for the submission of clinical trial results information. In addition, we note that we interpret the phrase ''estimated completion date,'' as such term is used in section 402(j)(3)(E)(i)(I) of the PHS Act, to have the same meaning as ''expected completion date,'' as such term is used in section 402(j)(2)(A)(ii)(I)(jj) of the PHS Act, because both indicate the date on which the responsible party anticipates that the clinical trial will be completed.

In addition, we believe it is important for users to have information about the actual completion date of a clinical trial, so that they can know when clinical trial results information ordinarily would be due under section 402(j)(3)(E)(i) of the PHS Act and proposed § 11.44(a), absent certain specified circumstances in which submission of clinical trial results information may be delayed. Because clinical trial results information generally is required under section 402(j)(3)(E)(i) of the PHS Act and proposed § 11.44 to be submitted not later than 1 year after the estimated or actual completion date, whichever is earlier, we believe it is important for the Completion Date data element to be updated promptly after the completion date is reached. We therefore propose in § 11.28(a)(1)(xvii) that when registering a clinical trial, a responsible party must submit the Completion Date for the clinical trial, which is defined in § 11.10(b)(17) to mean: ''the estimated completion date. Once the clinical trial has reached the completion date, the responsible party must update the Completion Date data element to reflect the actual completion date.'' The Completion Date must include the day, month, and year. We would require the responsible party to take the following steps with regard to the Completion Date data element: (1) Provide a reasonable estimated completion date at the time of registration; (2) update the estimated completion date at least once every 12 months during the course of the clinical trial, in accordance with proposed § 11.64(b)(1)(viii)(A), if the

estimate changes; and (3) update the Completion Date information to indicate the actual completion date not later than 30 days after the clinical trial reaches its completion date, in accordance with proposed § 11.64(b)(1)(viii)(B). Finally, we note that, consistent with the requirement in section 402(j)(4)(C)(ii) of the PHS Act, ClinicalTrials.gov will maintain an archive of all of the updates made to the Completion Date data element.

Enrollment. Section 402(j)(2)(A)(ii)(I)(kk) of the PHS Act expressly requires submission of ''the target number of subjects'' to be enrolled in an applicable clinical trial, but this phrase is not defined. We believe this data element is intended to describe the intended or estimated size of the clinical trial, in terms of the estimated total number of human subjects (including healthy volunteers) or target number of human subjects who will be enrolled in the clinical trial. We therefore propose in § 11.28(a)(1)(xviii) to require the submission of enrollment information at the time of registration, which is described in proposed § 11.10(b)(18) as ''the estimated total number of human subjects to be enrolled or target number of human subjects in the clinical trial.''

We expect that the estimated or target enrollment in a clinical trial might change either before or during the clinical trial, e.g., as recruitment continues. Consistent with section 402(j)(4)(C) of the PHS Act and proposed § 11.64(a)(1), a responsible party would be required to update the Enrollment data element not less than once every 12 months, if the anticipated or target enrollment in the clinical trial changes. This update would be in addition to the requirement in proposed § 11.64(b) that a responsible party submit the Actual Enrollment data element when recruitment for a clinical trial has ended, i.e., when the Overall Recruitment Status of the trial is changed to ''active, no longer recruiting'' or ''terminated.'' This latter requirement is intended to provide users of ClinicalTrials.gov with additional information about the total number of participants enrolled in the clinical trial, which may differ from the target enrollment. (See proposed § 11.64(b) and the discussion below of ''Overall Recruitment Status'' for a discussion of this requirement.) Our proposal for Enrollment is similar to procedures in place for ClinicalTrials.gov prior to FDAAA.

Primary Outcome Measures and *Secondary Outcome Measures* are data elements expressly required by section 402(j)(2)(A)(ii)(I)(ll) of the PHS Act to be submitted as part of clinical trial information at the time of registration. Definitions of the terms Outcome Measure, Primary Outcome Measure, and Secondary Outcome Measure are provided and elaborated upon earlier in this preamble and in proposed subpart A.

Section 402(j) of the PHS Act does not specify what specific information about primary and secondary outcome measures must be submitted to ClinicalTrials.gov at the time of registration. We therefore have attempted to develop requirements that are consistent with what we believe to be the intent of section 402(j) of the PHS Act, with data submission standards for ClinicalTrials.gov prior to passage in 2007 of section 402(j) of the PHS Act, and with our understanding of common practice in the clinical trials community.

Under proposed §§ 11.28(a)(1)(xix) and (xx), responsible parties would be required to submit the information specified in §§ 11.10(b)(19) and (20) for each primary or secondary outcome measure in their clinical trials, namely: (1) The name of the specific outcome measure (e.g., systolic blood pressure); (2) a description of the metric used to characterize the specific outcome measure (e.g., mean value of systolic blood pressure); and (3) the time point(s) at which the measurement is assessed for the specific metric used (e.g., 24 weeks after initiation of treatment). These requirements are consistent with the WHO Data Elements Version 1.2.1, which specifies that each outcome include the name of the outcome, the metric or method of measurement used, and the time point(s) of primary interest. Furthermore, based on our experience in operating ClinicalTrials.gov, we believe these three elements are key attributes of an outcome measure. Not only might certain outcome measures can be assessed in different ways (e.g., systolic blood pressure can be measured as a mean value or as a change from baseline), but also a single clinical trial may assess a single attribute at multiple points in time, e.g., systolic blood pressure may be measured 3 months, 6 months, and 12 months after beginning treatment. Each of these would be considered a different outcome measure. Ensuring that the primary and secondary outcome measures include descriptions of the measures and the time points of assessment is therefore necessary for differentiating between similar measures and for subsequently ensuring that results information is provided for all of them and in a manner that is consistent with the way in which they were pre-specified in the registry. It also ensures that any changes in the outcome measure are recorded as updates to the registration information, consistent with the purpose of the data bank ''to track subsequent progress of clinical trials,'' section 402(j)(2)(A)(i) of the PHS Act. Defining Primary Outcome Measure Information and Secondary Outcome Measure Information to include these three pieces of information also retains consistency with data submission prior to FDAAA, when those submitting information to ClinicalTrials.gov were requested to provide ''the specific measure that will be used to determine the effect of the intervention(s), along with the timeframe for taking measurements'' [Ref. 2].

(2) Recruitment Information

Eligibility criteria. Section 402(j)(2)(A)(ii)(II)(aa) of the PHS Act expressly requires ''eligibility criteria'' to be submitted for registration in ClinicalTrials.gov, but it does not define the term. We believe the purpose of this data element is to enable users of the data bank to determine key characteristics of potential participants in the clinical trial and to assist prospective participants in identifying clinical trials that may be of interest. Consistent with the stated objective of section 402(j)(2)(A)(i) of the PHS Act to ''enhance patient enrollment,'' we interpret the requirement to include an ''eligibility criteria'' data element as part of clinical trial registration information to refer to information that can be of practical use to prospective participants who wish to determine if they potentially qualify to participate in a clinical trial and who might be interested in seeking additional information about a clinical trial.

Clinical trial protocols typically contain lengthy, detailed descriptions of inclusion and exclusion requirements for participants, including, for example, specific laboratory test result values. The requirements are often complex and must be assessed by a clinician or researcher involved in the clinical trial. We believe the submission of all eligibility criteria would be burdensome for responsible parties and, instead of helping prospective participants, would instead prove confusing or overwhelming. We believe that prospective participants would be better served by including a more limited list of inclusion and exclusion criteria in the data bank, in order to assist prospective participants in identifying clinical trials of possible interest. Prospective participants who believe they meet the criteria listed in the data

bank could discuss the clinical trial with their physician or other healthcare advisor and contact the facility-specific contact or central contact for the clinical trial for more information and a more complete assessment of eligibility. While there may be other users of the data bank who wish to have more detailed information about eligibility criteria for purposes of interpreting clinical trial results information and better understanding the population of human subjects studied, they could request such information from the Results Point of Contact, whose information would be submitted under proposed § 11.48(a)(5), and/or request a copy of the protocol.

Therefore, in proposed § 11.10(b)(21), Eligibility Criteria is described as ''a limited list of criteria for selection of human subjects to participate in the clinical trial, provided in terms of inclusion and exclusion criteria and suitable for assisting potential human subjects in identifying clinical trials of interest.'' For entry of eligibility criteria information, we would prefer that responsible parties list inclusion and exclusion criteria (e.g., inclusion criteria: Clinical diagnosis of Alzheimer's Disease, and must be able to swallow tablets; exclusion criteria: Insulin dependent diabetes and thyroid disease).

Our proposed definition of ''eligibility criteria'' is consistent with ''key inclusion and exclusion criteria'' (data item #14) of the WHO Trial Registration standard (version 1.0) and ICMJE registration policies [Ref. 13, 10]. This proposed interpretation is also consistent with longstanding practice in ClinicalTrials.gov and the international clinical trial community. Prior to FDAAA, those submitting information to the ClinicalTrials.gov registry pursuant to FDAMA were requested to include ''key eligibility criteria'' for the trial [Ref. 4]. This term was defined to mean ''summary criteria for participant selection'' including inclusion and exclusion criteria [Ref. 2].

Gender. Section 402(j)(2)(A)(ii)(II)(bb) of the PHS Act expressly requires ''gender'' to be submitted as clinical trial information at the time of registration, but it does not define this term. In proposed § 11.10(b)(22) we define the term to mean, ''the biological sex of the human subjects who may participate in the clinical trial.'' This is consistent with practice prior to FDAAA, when those submitting information to the ClinicalTrials.gov registry were requested to include the gender of participants of the trial [Ref. 4], which was defined to mean, ''physical gender of individuals who may participate in the protocol'' [Ref. 2]. Responsible parties would select from the following limited set of choices: ''male,'' ''female,'' or ''both.'' No ''other'' option is proposed, but responsible parties would be able to provide voluntarily additional, free-text information about the gender of participants who may participate in the clinical trial.

Age limits. Section 402(j)(2)(A)(ii)(II)(cc) of the PHS Act expressly requires ''age limits'' to be submitted as a clinical trial information at the time of registration, but it does not define the term. In proposed § 11.10(b)(23) we define the term to mean, ''the minimum and maximum age of human subjects who may participate in the clinical trial, provided in relevant units of time.'' Examples of ''relevant units of time'' include but are not limited to years, months, or weeks. This description of age limits is consistent with that used prior to FDAAA, when those submitting information to the ClinicalTrials.gov registry were requested to include the age limits for participants in the trial [Ref. 4]. At that time, the term was defined to mean a ''minimum age'' and ''maximum age of participants'' using ''a number and a unit of time (years, months, weeks, days, hours or minutes)'' [Ref. 2].

Accepts Healthy Volunteers? Section 402(j)(2)(A)(ii)(II)(dd) of the PHS Act requires the submission of information about ''whether the trial accepts healthy volunteers.'' In proposed § 11.10(b)(24), we define a data element called Accepts Healthy Volunteers to mean ''whether human subjects who do not have a disease or condition, or related conditions or symptoms, under study in the clinical trial are permitted to participate in the clinical trial.'' This definition is consistent with practice prior to FDAAA, when those submitting information to the ClinicalTrials.gov registry were required to indicate ''if persons who have not had the condition(s) being studied or otherwise related conditions or symptoms, as specified in the eligibility requirements, may participate in the study'' [Ref. 4]. Note that we consider any human participant in a clinical trial to be a human subject regardless of whether he or she is a healthy volunteer.

Overall Recruitment Status. Section 402(j)(2)(A)(ii)(II)(ee) of the PHS Act requires ''overall recruitment status'' to be submitted as clinical trial information at the time of registration, but it does not define this term. Prior to FDAAA, those submitting registration information to ClinicalTrials.gov were requested to indicate the overall recruitment status of the trial [Ref. 4]. This term was defined to mean ''overall accrual activity for the protocol'' [Ref. 2]. This definition of overall recruitment status is consistent with ''recruitment status'' (data item #18) of the WHO Trial Registration standard (version 1.0) and ICMJE registration policies [Ref. 13, 10]. Therefore, under proposed § 11.10(b)(25) we define the Overall Recruitment Status data element as ''the recruitment status for the clinical trial as a whole, based upon the status of the individual sites. If at least one facility in a multi-site clinical trial has an individual site status of 'recruiting,' then the overall recruitment status for the trial must be 'recruiting.'

To facilitate user searching by recruitment status and allow information to be compared across clinical trials, responsible parties would be required to select from the following limited set of choices: ''Not yet recruiting'' (participants are not yet being recruited); ''Recruiting'' (participants are currently being recruited); ''Enrolling by invitation'' (participants are being, or will be selected from a predetermined population); ''Active, not recruiting'' (study is ongoing, meaning participants are being treated or examined, but new participants are not currently being recruited or enrolled); ''Completed'' (the study has concluded normally; participants are no longer being examined or treated, i.e., last patient's last visit has occurred); ''Suspended'' (recruiting or enrolling participants has halted prematurely but potentially will resume), ''Terminated'' (recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being examined or treated), and ''Withdrawn'' (study halted prematurely, prior to enrollment of first participant). No ''other'' option is proposed. We believe this list includes all relevant choices for Overall Recruitment Status, but we invite public comment on whether the proposed options are sufficient to accurately describe the Overall Recruitment Status of applicable clinical trials and other voluntarily registered clinical trials that would be subject to this proposed rule.

If a clinical trial is registered before it is open to enrollment, we would expect the Overall Recruitment Status to be listed as ''Not yet recruiting.'' When the clinical trial opens for enrollment, we would expect the Overall Recruitment Status to be listed as ''Enrolling by invitation'' if human subjects are selected from a predetermined population, or as ''Recruiting'' if the study is open to volunteers who meet the study's eligibility criteria. As

indicated in the discussion of the Study Start Date data element, in the context of this rulemaking, if a clinical trial is registered prior to enrollment of the first subject and the clinical trial is subsequently halted before the first subject is enrolled, we would expect the responsible party to update the Overall Recruitment Status data element to ''Withdrawn.''

When indicating that recruitment to a clinical trial has stopped, we believe it is important to distinguish between several different situations: (1) ''Active, not recruiting,'' in which enrollment has closed, but enrolled human subjects are continuing to be examined or treated according to the study protocol; (2) ''Completed,'' in which the clinical trial has concluded according to its protocol and human subjects are no longer being enrolled, treated, or examined; (3) ''Suspended,' in which the clinical trial is temporarily halted after one or more human subjects is enrolled but may potentially resume enrollment and in which enrolled human subjects may continue to be treated or examined; and (4) ''Terminated,'' in which the study is permanently halted after one or more subjects is enrolled in the clinical trial but before the trial is completed as anticipated in the protocol. We would therefore require responsible parties to provide such information. We believe that updating the Overall Recruitment Status data element would provide users of ClinicalTrials.gov with an effective means of tracking the progress of clinical trials, as the data bank is intended to do (section 402(j)(2)(A)(i) of the PHS Act). In the case of a clinical trial that is halted before the first subject is enrolled (i.e., withdrawn), this information would explain why no results information is to be expected or is required to be submitted. In the case of a clinical trial for which recruitment is prematurely halted (i.e., suspended or terminated), this information would allow potential human subjects to determine whether enrollment is likely to resume. Such information would also assist in the interpretation of results information, for example, by providing an explanation of why some clinical trial outcomes were not achieved and/or enrollment was significantly below the target.

Why Study Stopped? In situations in which a clinical trial is suspended, terminated, or withdrawn prior to its completion as anticipated by the protocol, we propose to require that responsible parties not only submit or update the Overall Recruitment Status data element but also provide a brief explanation for why the clinical trial was stopped. While this information is not required for submission by section 402(j) of the PHS Act, we believe it is important to communicate to users of the data bank why a clinical trial was suspended, terminated, or withdrawn, e.g., because of safety concerns, difficulties in recruitment, or for financial reasons. Such information also furthers the statutory objective stated in section 402(j)(2)(A)(i) of the PHS Act to enable users ''to track subsequent progress of clinical trials.'' For these reasons, requiring this information improves and does not reduce the clinical trial information available in the data bank, consistent with section 402(j)(2)(A)(iii) of the PHS Act.

In our experience operating ClinicalTrials.gov, we have found that users often wish to have information describing why a clinical trial stopped prematurely and that clinical trial sponsors often wish to submit such information voluntarily so they may explain why a clinical trial was prematurely stopped. We are concerned that if submission of this information is not required then some responsible parties might submit it selectively, resulting in users having information about why clinical trials are stopped for only some registered clinical trials. In order to reduce confusion and inconsistencies in the information available for registered clinical trials, we believe that submission of such information should be required in each instance in which a clinical trial is stopped prematurely (i.e., not according to the protocol). Accordingly, proposed §§ 11. 28(a)(2)(vi) and 11.64(b) specify that a brief explanation for why the clinical trial was stopped must be submitted if the overall recruitment status is ''suspended'' or ''terminated,'' or ''withdrawn.'' In most cases, the overall recruitment status of a clinical trial would be other than ''suspended,'' ''terminated,'' or ''withdrawn'' at the time of registration (e.g., ''not yet recruiting'' or ''recruiting''). The responsible party would not be required to complete the ''why study stopped'' data element unless and until there is a change in overall recruitment status to ''suspended,'' ''terminated,'' or ''withdrawn.'' (The Why Study Stopped data element would be presented neither to a responsible party during the registration process nor to the public in the posted clinical trial record, unless and until the overall recruitment status indicates that the clinical trial is ''suspended,'' ''terminated,'' or ''withdrawn''). However, we note that if a clinical trial is ''suspended,'' ''terminated,'' or ''withdrawn,'' the responsible party would be required to update the Overall Recruitment Status data element and, consistent with proposed § 11.64(b), submit the Why Study Stopped data element not later than 30 calendar days after the date of such suspension, termination, or withdrawal, to explain why the study stopped. We propose to allow responsible parties to enter this information as free-text, to provide them with the flexibility to explain the reason(s) why a clinical trial stopped prematurely. We define the data to be submitted in proposed § 11.1(b)(26) as ''for a clinical trial that is suspended or terminated or withdrawn prior to its completion as anticipated by the protocol, a brief explanation of the reason(s) why such clinical trial was stopped.''

Actual Enrollment. When enrollment of human subjects to a clinical trial ends because recruitment was completed in accordance with the protocol or because the clinical trial was terminated prior to its completion as anticipated by the protocol, we propose to require responsible parties to submit the actual number of human subjects enrolled in the clinical trial by completing the Actual Enrollment data element. The actual enrollment data element does not need to be completed until such time as the overall recruitment status data element is updated to ''active, not recruiting'' or ''terminated.'' See proposed § 11.64(b). (The Actual Enrollment data element would be presented neither to a responsible party during the registration process nor to the public in the posted clinical trial record, unless and until the overall recruitment status indicates that the clinical trial is ''active, not recruiting'' or ''terminated.'') We believe submission of actual enrollment information is consistent with the objective of the expanded registry data bank to ''provide a mechanism to track subsequent progress of clinical trials'' (section 402(j)(2)(A)(i) of the PHS Act). It would offer a means of measuring how actual enrollment compares with the target or estimated enrollment in the clinical trial (collected under proposed § 11.28(a)(1)(xviii)).

Our proposal would require a responsible party to submit the actual enrollment figure only after enrollment is closed. Although requiring more frequent updates while recruitment is ongoing would allow tracking of enrollment progress, we believe it would be burdensome for responsible parties, especially for clinical trials with multiple sites, and provide limited value to users. The data could become quickly outdated as enrollment for the clinical trial continues, potentially

leading users to believe that enrollment is lower than is the case. We believe that providing the actual enrollment figure once, at the time recruitment ends, would provide an effective means for tracking the progress of clinical trials registered in ClinicalTrials.gov. When combined with information about target enrollment, the actual enrollment data would indicate the degree to which the clinical trial met its enrollment target. By requiring the submission of actual enrollment data when enrollment closes, rather than when results information is submitted (which could be several years after enrollment closed), users would be able to gauge in advance their level of interest in the results of the clinical trial: The results of a clinical trial for which actual enrollment is substantially below the target enrollment might be of less interest than one in which recruitment targets were met. In proposed § 11.10(b)(27) we define Actual Enrollment as ''for a clinical trial for which recruitment of human subjects has terminated or completed, the actual number of human subjects enrolled in the clinical trial.''

Individual Site Status. Section 402(j)(2)(A)(ii)(II)(ff) of the PHS Act expressly requires ''individual site status'' to be submitted as a clinical trial information at the time of registration, but it does not define this term. Prior to FDAAA, those submitting information to the ClinicalTrials.gov registry were requested to include a recruitment status for each site of the trial [Ref. 4]. This term was defined to mean ''protocol accrual activity at a facility'' [Ref. 2]. In proposed § 11.28(a)(2)(viii), we would require the submission of Individual Site Status, which is defined in § 11.10(b)(28) as ''the recruitment status of each participating facility in a clinical trial.'' Consistent with the proposed Overall Recruitment Status data element, responsible parties would be required to indicate individual site status by selecting from the following limited set of choices: ''Not yet recruiting,'' ''Recruiting,'' ''Enrolling by invitation,'' ''Active, not recruiting,'' ''Completed,'' ''Suspended,'' ''Terminated,'' and ''Withdrawn.'' No ''other'' option is proposed, but we invite public comment on whether the proposed options are sufficient to accurately describe the Individual Site Status of applicable clinical trials and other voluntarily registered clinical trials that would be subject to this proposed rule. (See the discussion of Overall Recruitment Status for a description of these categories.)

Availability of Expanded Access. Section 402(j)(2)(A)(ii)(II)(gg) of the PHS Act specifies that, if a drug (including a biological product) being investigated in an applicable clinical trial is not approved under section 505 of the FD&C Act or licensed under section 351 of the PHS Act, the responsible party must specify: (1) ''whether or not there is expanded access to the drug under section 561 of the Federal Food, Drug, and Cosmetic Act for those who do not qualify for enrollment in the clinical trial''; and, if so, (2) ''how to obtain information about such access.'' We believe the purpose of this requirement is to allow prospective human subjects and other users of the data bank to readily identify unapproved drugs that are available through an expanded access program under section 561 of the FD&C Act and to be directed to additional information about the expanded access program. Therefore, we propose that responsible parties meet the requirements of section 402(j)(2)(A)(ii)(II)(gg) by indicating in the clinical trial record whether expanded access is available for the drug under study (i.e., ''yes'' or ''no'') and, if so, submitting the additional information about the expanded access in the form of an expanded access record under proposed § 11.28(c) and including the NCT number for the expanded access record in the record of a clinical trial that studies the drug.

We propose to require the submission of information to create an Expanded Access record using the statutory authority at section 402(j)(2)(A)(iii) of the PHS Act, which allows the Secretary by regulation to modify the requirements for clinical trial registration information if the Secretary provides a rationale for why such a modification ''improves and does not reduce such clinical trial information.'' Information about the availability of expanded access is a data element that a responsible party is required to submit under section 402(j)(2)(A)(ii)(II) and thus meets the definition of ''clinical trial information'' in section 402(j)(1)(A)(iv). We believe the additional data elements describing expanded access would improve and not reduce this clinical trial information by providing users with more complete and consistent information about expanded access programs for drugs studied in applicable clinical trials than would be available pursuant to section 402(j)(A)(ii)(II)(gg) of the PHS Act alone. We further conclude that we have authority to require that the clinical trial information required under proposed § 11.28(c) be submitted by creating a separate expanded access record in ClinicalTrials.gov under section 402(j)(2)(B)(iv) of the PHS Act, as the expanded access record will ensure that the public may more easily use the data bank to determine whether there is expanded access to a drug and to compare different expanded access programs.

Prior to FDAAA, those submitting information to the ClinicalTrials.gov registry were requested to submit a description of whether and through what procedure, the manufacturer or sponsor will respond to requests for protocol exception, with appropriate safeguards, for single-patient and expanded access use of the investigational drug, particularly in children [Ref. 3]. The data bank also permitted submission of information about expanded access to devices. At that time, the data bank included a ''Has Expanded Access?'' data field, which asked data submitters to ''indicate whether any non-protocol access is to be provided for the investigational drug or device.'' If expanded access were available, data submitters were requested to create an expanded access record via ClinicalTrials.gov. These expanded access records provided information to users of ClinicalTrials.gov about treatment access to investigational drugs or devices for patients for whom there was no satisfactory therapy available for their condition or who were unable to participate in ongoing clinical trials. Expanded access records were used to register all types of non-protocol access to investigational treatments [Ref. 2].

We propose a similar approach in this rule. Proposed § 11.28(a)(2)(ix) would require the responsible party for an applicable clinical trial of a drug that is not approved under section 505 of the FD&C Act to submit the Availability of Expanded Access data element, which is defined in proposed § 11.10(b)(29) to include ''[a]n indication of whether there is expanded access to the drug under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) for those who do not qualify for enrollment in the applicable clinical trial,'' and if expanded access is available, ''the NCT number of the expanded access record.'' The availability of expanded access would be indicated via a yes/no designation in ClinicalTrials.gov. If the NCT number is not available, because an expanded access record has not yet been created, the responsible party would enter ''pending'' for the NCT number.

In addition, if the drug studied in the clinical trial is available through expanded access under section 561 of the FD&C Act and an expanded access record has not been created, the

responsible party would be required to create an expanded access record, consisting of the information specified in proposed § 11.28(c). As was the case prior to FDAAA, the manner in which the responsible party would submit the data elements describing the expanded access program would be to create an expanded access record in ClinicalTrials.gov. Upon completion of the quality control process for the expanded access record, the expanded access record would be assigned its own NCT number and thus would be searchable and retrievable independent of the record(s) for the applicable clinical trial(s) of the investigational product for which expanded access is available. We would expect the sponsor of the expanded access program to be responsible for informing the responsible party(ies) of any applicable clinical trial that studies the drug available under expanded access that an expanded access record has been created and providing them with the NCT number for the expanded access record. The responsible party(ies) would be required to update the related clinical trial record under proposed § 11.64(b) to include the NCT number for the expanded access record within 30 days of receipt. Accordingly, a single expanded access record could be linked, via the expanded access record NCT number, to several applicable clinical trials that study the drug that is available via expanded access.

If an expanded access record has already been completed at the time of registration of an applicable clinical trial (e.g., to fulfill the registration or updating requirements for a previously registered applicable clinical trial), the responsible party would be required to submit the NCT number for that expanded access record as part of the Availability of Expanded Access data element. If an expanded access program is in place but an expanded access record has not been created at the time an applicable clinical trial of a drug is registered, the responsible party would not be required to submit the expanded access data elements under proposed § 11.28(c) prior to the date on which clinical trial registration information under proposed § 11.28(a) is due (i.e., in order to have the expanded access program NCT number available at the time of registration of the applicable clinical trial). Rather, the responsible party would be required at the time of registration to indicate that expanded access is available, to submit the data elements required by § 11.28(c), and to indicate that the NCT number for the expanded access record is ''pending.'' As described previously, within 30 days of receipt of the NCT number for the expanded access record, the responsible party would be required to update the applicable clinical trial record with the NCT number assigned to the Expanded Access record.

We note that expanded access is available via treatment INDs, which provide widespread access, expanded access for intermediate-size patient populations, and expanded access for individual patients. Because requests for individual patient access generally are handled on a case-by-case basis, a responsible party likely would not be able to provide detailed information describing individual patient access at the time of registering an applicable clinical trial. In cases where expanded access is only available for individual patients on a case-by-case basis, we would not require the responsible party to submit the expanded access record, as described below, and we expect that users of ClinicalTrials.gov may direct inquiries regarding individual patient access to the facility contact.

Finally, we note both that expanded access to a drug may not be available at the time an applicable clinical trial is registered and that an expanded access program may be discontinued on a date other than the completion date of an applicable clinical trial. We believe that information about changes in the availability of expanded access should be conveyed to users of ClinicalTrials.gov in a timely manner and thus that the availability of expanded access is a data element that should be updated more frequently than once every 12 months. Accordingly, as explained in further detail in section IV.D.3 of this preamble, we propose that the availability of expanded access data element be updated within 30 calendar days of either the initiation or termination of an expanded access program, consistent with proposed § 11.64(b).

(3) Location and Contact Information

Name of the Sponsor. Section 402(j)(2)(A)(ii)(III)(aa) of the PHS Act expressly requires responsible parties to submit the name of the sponsor as part of clinical trial information at the time of registration. Proposed § 11.28(a)(3)(i) implements this provision. In this part, the term ''sponsor'' is defined as ''either a 'sponsor' or 'sponsor-investigator,' as each is defined in 21 CFR 50.3, or any successor regulation.'' If the sponsor is a sponsor-investigator, we would expect the name of the sponsor to be the name of an individual; otherwise the name of the sponsor may be an organizational name. Hence, in proposed § 11.10(b)(30), Name of the Sponsor is defined as ''the name of the entity or the individual that is the sponsor of the clinical trial, as defined in § 11.10(a).''

Responsible Party, by Official Title. Section 402(j)(2)(A)(ii)(III)(bb) of the PHS Act expressly requires the submission of the ''responsible party, by official title'' as part of clinical trial registration information. We recognize that the responsible party for an applicable clinical trial may be the sponsor of the clinical trial (a term defined by this regulation to include the sponsor or the sponsor-investigator, as each is defined in 21 CFR 50.3) or a designated principal investigator. A responsible party that is the sponsor will typically be an organizational entity (e.g., a drug or device manufacturer that is the sponsor of an applicable clinical trial). A responsible party that is a sponsor-investigator will be an individual. A responsible party that is a designated principal investigator will be an individual. When an organizational entity is the responsible party, we believe that the official name of the entity (e.g., company name, university name, name of government agency) should be included to satisfy the requirement for the Responsible Party, by Official Title. When the responsible party is an individual, we believe that the official job title and the organizational affiliation of the individual are necessary (e.g., ''Director of Clinical Research, Institution X'' or ''Professor of Medicine, Institution Y''). In addition, we believe it is important to ask whether the responsible party is the sponsor, sponsor-investigator, or a principal investigator designated by the sponsor, grantee, contractor, or awardee. Collection of this information will help determine what information must be provided for the official title and will allow a principal investigator to provide an affirmative acknowledgement that he or she has been designated the responsible party. In light of these considerations, proposed § 11.10(b)(31) defines Responsible Party, by Official Title to mean an ''[i]ndication of whether the responsible party is the sponsor of the clinical trial, as that term is defined in 21 CFR 50.3, the sponsor-investigator, as that term is defined in 21 CFR 50.3, or a principal investigator designated pursuant to this part'' (this indication would be provided by selecting among these three options) and either ''the official name of the entity'' if the responsible party is an organizational entity, or ''the official title and primary organizational affiliation of the individual'' if the responsible party is an individual. An

individual who serves as a responsible party and has multiple affiliations (e.g., a research university and a teaching hospital, or a research institution and a private company), would be required to submit only one such affiliation; namely, the affiliation they consider their primary affiliation. We note that proposed § 11.10(b)(38) defines a related data element, Responsible Party Contact Information.

Facility Information. Section 402(j)(2)(A)(ii)(III)(cc) of the PHS Act expressly requires the submission of ''the facility name and facility contact information'' as part of clinical trial information at the time of registration and describes facility contact information as ''including the city, State, and zip code for each clinical trial location, or a toll-free number through which such location information may be accessed.'' In considering how to implement this provision, we took into consideration section 402(j)(2)(B)(i) of the PHS Act, which requires the Director to ensure that the public may search the entries in ClinicalTrials.gov by one or more of several enumerated criterion, one of which is ''location of the clinical trial.'' We interpret ''location of the clinical trial'' in this context as meaning each location of the clinical trial because section 402(j)(2)(A)(ii)(III)(cc) of the PHS Act describes ''facility contact information'' as meaning contact information ''for each clinical trial location.'' In order for users of ClinicalTrials.gov to be able to search the data bank by each location of the clinical trial, the responsible party must submit to the data bank the location of each facility at which the applicable clinical trial is conducted. In our view, a toll-free telephone number is not a substitute for the location information for each facility or site but rather is a source of supplementary information about the clinical trial overall and an alternative to site-specific contact information for each location.

For these reasons, we believe including this information improves and does not reduce the clinical trial registration information. Under our authority in section 402(j)(2)(A)(iii) of the PHS Act, we therefore propose in § 11.28(a)(3)(iii) to modify the requirement in section 402(j)(2)(A)(ii)(III)(cc) of the PHS Act for ''facility name and facility contact information'' to require Facility Information for each participating facility in the clinical trial, which we define in proposed § 11.10(b)(32) as (1) ''Facility Name, meaning the full name of the organization where the clinical trial is being conducted''; (2) ''Facility Location, including city, state, country and zip code for U.S. locations (including territories of the United States) and city and country for locations in other countries,'' and (3) either ''[for each facility location submitted], a Facility Contact, including the name or title, telephone number, and email address of a person to whom questions concerning the trial and enrollment at that site can be addressed,'' or a ''Central Contact person, including the name or title, toll-free telephone number and email address of a person to whom questions concerning enrollment at any location of the trial can be addressed.''

As noted above, the Agency intends to exercise its authority under section 402(j)(2)(B)(i) to enable the public to search the data bank by the location of the clinical trial and, in our view, satisfactory searching by location can only be accomplished if responsible parties submit complete facility location information for each clinical trial location. In addition, our proposal to allow (but not require) responsible parties to submit the name or title of a person knowledgeable about the clinical trial at each site, along with the phone number and email address of that person, would help prospective human subjects obtain additional, specific information about a clinical trial at a particular location. Our proposal to permit responsible parties to submit a Central Contact in lieu of Facility Contact is intended to reduce the burden on responsible parties who must submit clinical trial registration information. However, the central contact person should be fully informed of, and able to respond to, requests for information concerning the clinical trial at all of its sites. This approach is similar to the one used prior to FDAAA, when those submitting information to the ClinicalTrials.gov registry were requested to include each facility name and facility contact information for the registered clinical trial and were permitted to include a ''central contact'' rather than contact information for each facility of the trial [Ref. 4]. At the time, the term ''facility name'' was defined to include the ''full name of the organization where the protocol is being conducted'' and central contact was defined as a ''person providing centralized, coordinated recruitment information for the entire study'' [Ref. 2].

(4) Administrative Data

Section 402(j)(2)(A)(ii)(IV) of the PHS Act provides for certain ''administrative data'' to be submitted by responsible parties as part of clinical trial registration information; however, unlike the other categories of clinical trial registration information, the statute specifies that the Secretary may make administrative data ''publicly available as necessary.'' Accordingly, in the descriptions below of each administrative data element, the Agency indicates whether it proposes to make the information publicly available through ClinicalTrials.gov.

Unique Protocol Identification Number. Section 402(j)(2)(A)(ii)(IV)(aa) of the PHS Act expressly requires the submission of ''the unique protocol identification number'' as part of clinical trial information at the time of registration, but it does not define the term. We propose in § 11.10(b)(33) to define ''unique protocol identification number'' as ''any unique identification number assigned to the protocol by the sponsor.'' Once entered into ClinicalTrials.gov, that unique protocol identification number cannot be assigned to another protocol for another clinical trial in the sponsor's ClinicalTrials.gov account. In cases in which multiple identification numbers may have been assigned to a clinical trial (e.g., a funding organization's grant number, a unique identifier established by another clinical trial registry), we believe that interpreting this term as a number ''assigned by the sponsor'' will remove any ambiguity for responsible parties about which number to submit as the unique protocol identification number for purposes of registration on ClinicalTrials.gov. We also expect that the unique protocol identification number would be readily available to the responsible party, whether the sponsor or a designated PI, who would have access to the protocol itself and/or be able to obtain the unique protocol number from the sponsor. Further, these numbers often are used in other clinical trial documentation, which will enable cross-referencing of information submitted to different data systems. To enable such cross-referencing, we plan to make this data element publicly available in ClinicalTrials.gov.

This approach is consistent with that used in ClinicalTrials.gov prior to FDAAA, when those submitting information to the registry were requested to include the unique protocol ID of the trial [Ref. 4]. This term was defined to mean any ''unique identification assigned to the protocol by the sponsoring organization, usually an accession number or a variation of a grant number. Multiple studies conducted under the same grant must each have a unique number'' [Ref. 2]. The wording of our proposed description modifies the previous one by, among other things, removing the

reference to ''a variation of a grant number'' because all grant-related information is proposed to be collected under the Secondary IDs data element.

Secondary IDs. Section 402(j)(2)(A)(ii)(IV)(bb) of the PHS Act expressly requires the submission of ''other protocol identification numbers, if any,'' at the time of registration, but does not define this term. Prior to FDAAA, those submitting information to ClinicalTrials.gov were requested to include secondary IDs of the clinical trial. This term was defined as ''other identification numbers assigned to the protocol, including ISRCTN . . . and NIH grant numbers, if applicable'' [Ref. 2]. This definition is consistent with ''secondary identification number(s)'' (data item #3) of the WHO Trial Registration standard (version 1.0) and ICMJE registration policies [Ref. 13, 10]. To maintain consistency with these widely used terms and definitions, we propose in proposed § 11.10(b)(34) to define the term, in part, as ''[a]ny identification number(s) other than the organization's unique protocol identification number or NCT number that is assigned to the clinical trial . . .'' We also propose that the Secondary IDs include ''any unique clinical trial identification numbers assigned by other publicly available clinical trial registries,'' such as EudraCT in the European Union. We intend to post publicly the Secondary IDs, as such information will enable users to locate additional information about the clinical trial that may be included in other registries; it also will enable users to determine if registration information listed in another registry refers to the same trial that is registered in ClinicalTrials.gov, thereby avoiding potential confusion.

In addition, we propose that Secondary IDs include the complete grant or contract number for any clinical trial that is funded, in whole or in part, by a U.S. federal government agency. This requirement would enable users of ClinicalTrials.gov to identify government-funded clinical trials. It also would assist agencies of the Department (including NIH, FDA, CDC, and the Agency for Healthcare Research and Quality) to verify that clinical trial information for each applicable clinical trial for which a grantee is the responsible party has been submitted consistent with sections 402(j)(2) and (3) of the PHS Act and this proposed Part before they release any remaining funding for a grant or provide funding for a future grant to such grantee. Such verification procedures are required under section 402(j)(5)(A)(ii) of the PHS Act of any agency of the Department that funds applicable clinical trials. In addition, although the requirement of section 402(j)(5)(A)(ii) of the PHS Act applies only to the agencies of the Department, the inclusion of grant and contract numbers for awards from other federal agencies (e.g., Department of Veterans Affairs, Department of Defense) would facilitate efforts by the Secretary, as required under section 402(j)(5)(A)(iv) of the PHS Act, to consult with such other agencies and to develop comparable procedures for verification of compliance with the requirements of sections 402(j)(2) and (3) of the PHS Act.

Finally, in order that users can interpret the various Secondary IDs that might be provided in response to this requirement, we propose to require responsible parties to submit ''[a] description of the type of Secondary ID'' for each Secondary ID submitted. These descriptions should be brief, but should clearly indicate the source of the identifier, e.g., ''U.S. NIH Grant Number'' or ''[XYZ] Registry Identifier.'' To facilitate data entry and improve comparability across registered clinical trials, we will include a list of several common identifier types in ClinicalTrials.gov, while permitting free-text entries, as well. Currently, ClinicalTrials.gov allows responsible parties to select from the following options: ''US NIH Grant/Contract Award Number,'' ''Other Grant/Funding Number,'' ''Registry Identifier,'' ''EudraCT Number,'' and ''Other Identifier.'' Responsible parties who select ''Other Grant/Funding Number,'' ''Registry Identifier,'' or ''Other Identifier'' are required to enter the name of the granting organization or a brief description of the identifier.

Food and Drug Administration IND or IDE number. Section 402(j)(2)(A)(ii)(IV)(cc) of the PHS Act expressly requires the ''Food and Drug Administration IND/IDE protocol number'' to be submitted to ClinicalTrials.gov at the time of registration in ClinicalTrials.gov, but it does not define this term. FDA does not issue an ''IND/IDE protocol number,'' as referred to in section 402(j)(2)(A)(ii)(IV)(cc) of the PHS Act; rather it issues an IND or IDE number. We therefore propose to use the term ''Food and Drug Administration IND or IDE number'' to identify this data element in ClinicalTrials.gov. We also recognize that not all applicable clinical trials will be conducted under an IND or IDE (e.g., because they are exempt).

Because CDER, CBER, and CDRH each issues IND or IDE numbers using a similar format, we believe that, for purposes of registration with ClinicalTrials.gov, a complete, unambiguous IND or IDE number must include the name of the FDA center that issued it. In addition, if several clinical trials are conducted under a single IND, for example, each such clinical trial may have a different serial number assigned to it. We believe that any such serial number must also be specified to avoid confusion. Moreover, if multiple serial numbers are assigned to a single IND (e.g., to reflect different clinical trials, protocols, or protocol amendments), the responsible party should submit only the first serial number that corresponds to the clinical trial being registered.

Taking the foregoing into consideration, we propose in § 11.10(b)(35) to define the Food and Drug Administration IND or IDE Number data element to include an indication whether or not there is an IND or IDE for the clinical trial (a yes/no response) and, if so, each of the following elements: (1) ''Name or abbreviation of the FDA center with whom the IND or IDE is filed;'' (2) ''IND or IDE number assigned by the FDA center;'' and (3) for an IND, ''the IND serial number (as defined in 21 CFR 312.23(e), or any successor regulation), if any, assigned to the clinical trial.'' In specifying the FDA center with which the IND or IDE is filed, responsible parties would select from the following limited set of options: CDER, CBER, or CDRH. These abbreviations correspond to the FDA Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, and Center for Devices and Radiological Health, respectively, which are the three FDA centers with which INDs and IDEs are filed.

Our proposed approach for IND or IDE numbers is consistent with that used prior to FDAAA, when those submitting information to the ClinicalTrials.gov registry were requested to include ''the IND number and serial number and designate whether the IND is located in the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER)'' [Ref. 4]. Also consistent with previous ClinicalTrials.gov practice, we do not intend to make the Food and Drug Administration IND or IDE number available to the public. Section 402(j)(2)(A)(ii)(IV) of the PHS Act indicates that administrative data submitted as part of clinical trial information may be made publicly available ''as necessary.'' We do not consider public posting of information in this field to be necessary for the effective use of ClinicalTrials.gov or for

understanding of the information submitted.

Human Subjects Protection Review Board Status. We propose to require the submission of information about human subjects protection review board status as part of clinical trial information. Submission of this information is not required by section 402(j) of the PHS Act, but we propose to add this requirement pursuant to the authority given by section 402(j)(2)(A)(iii) of the PHS Act to modify the requirements for clinical trial registration information if such modification ''improves and does not reduce such clinical trial information.'' We believe that submission of the Human Subjects Protection Review Board Status, as specified below, to ClinicalTrials.gov would improve and not reduce clinical trial information by indicating to users of the data bank whether a clinical trial registered in ClinicalTrials.gov is undergoing or has undergone human subjects protection review board review.

We believe that the submission of Human Subjects Protection Review Board Status is consistent with the purpose of the data bank ''to enhance patient enrollment,'' as described in section 402(j)(2)(A)(i) of the PHS Act. While review and approval by a human subjects protection review board, such as an IRB, cannot guarantee the scientific merit of a clinical trial or the safety of human subjects enrolled in it, it may provide some assurance that such factors are considered by a group of individuals who are not directly involved in the conduct of the clinical trial and who are charged to consider the safety of human subjects. Inclusion of such information in ClinicalTrials.gov would demonstrate to potential human subjects whether the clinical trials they find in ClinicalTrials.gov have undergone at least one human subjects protection review board review, have received necessary approvals for human subjects research from at least one human subjects protection review board, or were exempt from such review. For clinical trials conducted in the United States or under an IND or IDE, human subjects review would be conducted by an IRB as described in 45 CFR 46 and 21 CFR 50 and 56, as applicable, or any successor regulations. For clinical trials conducted outside the United States, we would expect the review to be conducted by a human subjects protection review board that is charged with providing independent ethics review that is aimed at ensuring the protection of the rights, safety, and well-being of human subjects involved in a clinical investigation by a group that is adequately constituted to provide assurance of that protection.

Inclusion of this data element is consistent with longstanding Agency practice. Prior to FDAAA, those submitting information to ClinicalTrials.gov were requested to include information regarding human subjects review [Ref. 4]. Human subjects protection review board approval information was not required to be submitted if the data submitter indicated that the trial was conducted under an IND or IDE because IRB approval is a requirement for conducting a clinical trial under an IND or IDE. We therefore interpreted the presence of an IND or IDE number as an acceptable indication that the trial had received necessary human subjects protection review board review. For trials not conducted under an IND or IDE, data providers were requested to submit information for only one human subjects protection review board even if multiple boards had reviewed the trial. Although it did not provide information on the status of review by every human subjects protection review board with authority over a trial, we viewed submission of information about one human subjects protection review board as establishing a minimum floor for studies listed in ClinicalTrials.gov by indicating whether they had been approved by at least one human subjects protection review board, or were seeking approval from such a board, or were exempt from such review.

Our current proposal requires submission of Human Subjects Protection Review Board Status for all applicable clinical trials and other clinical trials registered with ClinicalTrials.gov, but it does not require information about the specific review board. Under proposed § 11.28(a)(4)(v), responsible parties would be required to submit Human Subjects Protection Review Board Status as part of clinical trial information at the time of registration. We define Human Subjects Protection Review Board Status in § 11.10(b)(36) as ''information to indicate whether a clinical trial has been approved by a human subjects protection review board or is exempt from human subjects protection review board approval, . . .'' Human Subjects Protection Review Board Status would be provided by the Responsible Party selecting from a limited set of options described in ClinicalTrials.gov that are intended to cover all of the possible types of status: ''Request not yet submitted'' (review board approval is required but has not yet been requested); ''Submitted, pending'' (review board approval has been requested but not yet granted); ''Submitted, approved'' (review board approval has been requested and obtained); ''Exempt'' (an exemption in accord with applicable law and regulation has been granted); ''Submitted, denied'' (review board has denied the approval request); and ''Submission not required'' (review board approval is not required because the study is not subject to laws, regulations, or applicable institutional policies requiring human subjects review). No ''other'' option is proposed. We request comment on whether the above menu of options adequately captures all possible types of review status for applicable clinical trials and voluntarily registered trials that would be subject to this regulation. The status must be listed as ''approved'' if at least one human subjects protection review board has approved the clinical trial. An applicable clinical trial could be registered prior to human subjects protection review board approval by indicating that the status is, for example, pending, not yet submitted, or exempt. If the status subsequently changes, the responsible party would be required, consistent with proposed § 11.64(b), to update the Human Subjects Protection Review Board Status not later than 30 calendar days after the change.

Consistent with longstanding practice, responsible parties would be required to indicate that the clinical trial is approved when at least one human subjects protection review board has granted approval. To clarify for users that the human subjects protection review board status pertains to only one human subjects protection review board, we would indicate that fact in ClinicalTrials.gov and instruct potential human subjects to communicate with the site-specific point-of-contact or the central contact for the clinical trial (included as part of the Facility Information that is submitted as part of clinical trial information under proposed § 11.28(a)(3)(iii)) in order to determine the status of human subjects protection review board review at other sites of interest. We believe this approach will provide users with important information about human subjects review without burdening responsible parties with updating information on multiple sites.

Our proposal deviates from current practice with regard to the information that would be necessary for clinical trials conducted under an IND or IDE. We considered maintaining the current requirement that human subjects protection review board information (which is currently more extensive than

the single status element) be submitted only for clinical trials that are not conducted under an IND or IDE. We believe, however, that there would be an advantage in applying a consistent requirement across all registered clinical trials. Doing so would reduce confusion among responsible parties who might otherwise face different information submission requirements for different clinical trials and among users who might not be sure why certain clinical trials contain human subjects review information but others do not (as indicated above, we do not propose to make information about IND or IDE numbers publicly available in the data bank). We do not expect the burden of providing the human subjects protection review board status for a particular clinical trial to be significant, especially as it would be limited to a single data element about one human subjects protection review board.

Record Verification Date is a data element required by section 402(j)(2)(A)(ii)(IV)(cc) of the PHS Act to be submitted as part of clinical trial information at the time of registration, but the statute does not define this term. The statutory provision calls for the submission of ''the Food and Drug Administration IND/IDE protocol number and the record verification date.'' We believe record verification date is intended to be submitted as a separate data element that indicates to users of the data bank how recently the information for a particular clinical trial was verified and, hence, whether or not it may be out of date. We therefore intend to collect and post publicly the Record Verification Date data element in ClinicalTrials.gov. Our interpretation of this term is consistent with that used prior to FDAAA when those submitting information to the registry were requested to list the ''record verification date'' of the trial, meaning the ''date the protocol information was last verified'' [Ref. 4].

We propose to require responsible parties to include the Record Verification Date data element as part of an initial submission of clinical trial registration information to ClinicalTrials.gov and to update it any time the responsible party reviews the complete clinical trial record for accuracy, such as when making a periodic review of an entire clinical trial record. For example, if a responsible party examines the entire record as part of a monthly or annual review and determines that no additional or updated information needs to be submitted, the responsible party would be required to update the Record Verification Date data element to indicate the date on which the review occurred. Or, if a responsible party updates a data element and also reviews the rest of the record for accuracy, the responsible party would also be required to update the Record Verification Date data element. However, if the responsible party submits updates to one or more data elements without reviewing the accuracy of the rest of the record, the Record Verification Date would not be updated. This proposal would not require a responsible party to review records more frequently or regularly than would be needed in order to update submitted information as specified in proposed § 11.64 (should the responsible party use this method to help ensure that updates are submitted on time), but it would require that the Record Verification Date be updated if the complete record were reviewed for accuracy during such an update. This proposal is consistent with current practice. Starting prior to FDAAA, those submitting data to ClinicalTrials.gov were requested to update the verification date when reviewing the record for accuracy and completeness, even if no other changes were made'' [Ref. 2]. At the time, we also suggested that records be reviewed at least every six months to help ensure that information available to the public in the data bank was up-to-date. Under proposed § 11.10(b)(37), we define Record Verification Date as ''the date upon which the responsible party last verified the clinical trial information in the entire ClinicalTrials.gov record for the clinical trial, even if no additional or updated information was submitted at that time.''

Responsible Party Contact Information. Section 402(j)(1)(B) of the PHS Act requires the Secretary to develop a mechanism ''by which the responsible party for each applicable clinical trial shall submit the identity and contact information of such responsible party to the Secretary at the time of submission of clinical trial information . . .'' We propose that the mechanism whereby the responsible party communicates the identity and contact information to the Secretary shall be via submission of such information at the time clinical trial information is first submitted to Clinical Trials.gov. Using the authority in section 402(j)(2)(A)(iii) of the PHS Act, we propose to modify the requirements for clinical trial information submitted at the time of registration to require responsible parties to submit Responsible Party Contact Information. In proposed § 11.10(b)(38), we describe Responsible Party Contact Information as ''[a]dministrative information to identify and allow communication with the responsible party by telephone, email, and regular mail or delivery service. Responsible Party Contact Information includes the name, official title, organizational affiliation, physical address, mailing address, phone number, and email address of the individual who is the responsible party or of a designated employee of the organization that is the responsible party.'' We believe that the addition of this information will improve and not reduce clinical trial information by providing a mechanism for the Agency to communicate with the responsible party about submitted information, which can improve its quality, accuracy and completeness. We do not intend to post the physical address, mailing address, phone number or email address of the responsible party. The system will contain other information, such as central or site-specific contact information that interested parties can use to request additional information about a clinical trial or inquire about participation. In general, we do intend to post the name of the responsible party if the responsible party is an individual, e.g., a sponsor-investigator who holds the IND or IDE for a clinical trial or a designated principal investigator. We would post the name of the responsible party, along with the Responsible Party, By Official Title, which section 402(j)(2)(A)(ii)(III)(bb) of the PHS Act requires to be made publicly available. We believe that posting of the individual's name is necessary to avoid ambiguity, e.g., if the responsible party is a university professor, there might be numerous individuals with the same title and affiliation (professor of medicine at ABC University). Posting the name of the individual when the individual is the responsible party would also be consistent with posting of the name of an entity when an entity is the responsible party of an applicable clinical trial. Responsible Party Contact Information would be required to be updated as specified in proposed § 11.64.

(b) Data elements required to register a pediatric postmarket surveillance of a device that is not a clinical trial. Proposed § 11.28(b) specifies the clinical trial information that must be submitted to ClinicalTrials.gov to register a pediatric postmarket surveillance of a device that is not a clinical trial as defined in this part, but is required to be registered under proposed § 11.22. Section 801(c) of

FDAAA recognizes that not all of the clinical trial information specified in section 402(j) of the PHS Act or proposed in this rule will apply to all pediatric postmarket surveillances of a device and directs the Secretary to issue guidance explaining how the registration and results submission provisions of section 402(j) of the PHS Act apply to a pediatric postmarket surveillance of a device that is not a clinical trial. The Agency intends this and the other discussions in this preamble related to pediatric postmarket surveillances of a device to serve as draft guidance that will be finalized when the final rule is issued.

In 21 CFR 822.3, ''postmarket surveillance'' is defined as the ''active, systematic, scientifically valid collection, analysis, and interpretation of data or other information about a marketed device.'' The Agency interprets a pediatric postmarket surveillance of a device as a postmarket surveillance of a device used in a pediatric population (i.e., patients who are 21 years of age or younger at the time of diagnosis or treatment). (*See* 21 U.S.C. 360j(m)(6)(E)). The clinical trial information specified in proposed § 11.28(a) and defined in proposed § 11.10(b), would apply to any pediatric postmarket surveillance of a device that is a clinical trial (i.e., Study Type would be ''interventional''). However, because not all pediatric postmarket surveillances under section 522 of the FD&C Act are clinical trials, as defined in this part, many of the data elements listed in proposed § 11.28(a) or the definitions proposed in § 11.10(b) might not apply to them. Therefore, proposed § 11.28(b) specifies a more limited set of data elements required to register a pediatric postmarket surveillance of a device that is not a clinical trial; moreover, it also modifies the definitions of certain of the data elements that are defined in § 11.10(b).

As set forth in proposed § 11.28(b), to register a pediatric postmarket surveillance of a device that is not a clinical trial, the responsible party must provide the following data elements: (1) Brief Title; (2) Official Title; (3) Brief Summary; (4) Study Type; (5) Whether the Study is a Pediatric Postmarket Surveillance of a Device; (6) Primary Disease or Condition Being Studied, or the Focus of the Study; (7) Intervention Name(s); (8) Other Intervention Name(s); (9) Intervention Description; (10) Intervention Type; (11) Study Start Date; (12) Completion Date; (13) Name of the Sponsor; (14) Responsible Party, by Official Title; (15) Contact Information; (16) Unique Protocol Identification Number, if any; (17) Secondary IDs; (18) Human Subjects Protection Review Board Status; (19) Record Verification Date; and (20) Responsible Party Contact Information. Consistent with the elaboration of these data elements in section IV.B.4 of this preamble, for a pediatric postmarket surveillance of a device that is not a clinical trial the Study Type must be designated as ''observational'' and Whether the Study is a Pediatric Postmarket Surveillance of a Device must indicate ''yes.''

In general, the definitions of these data elements are consistent with the definitions of the named data elements in proposed § 11.10(b); however, we have modified them, where appropriate, to better match the characteristics of pediatric postmarket surveillances of a device that are not clinical trials. For example, Study Start Date, which is defined in proposed § 11.10(b)(16) for a clinical trial as ''the estimated date on which a clinical trial will be open to enrollment of human subjects, or the actual date on which the first human subject was enrolled, is defined in proposed § 11.28(b)(1)(xi) as the ''date on which FDA approves the postmarket surveillance plan, as specified in 21 CFR 822.19(a) (or any successor regulation).'' Similarly, the definition of Completion Date in section 402(j)(1)(A) of the PHS Act and proposed § 11.10(b)(17) generally would not apply to a pediatric postmarket surveillance of a device that is not a clinical trial; hence, in proposed § 11.28(b)(1)(xii), we propose to require submission of the Completion Date data element, which is defined as ''[t]he estimated date on which the final report summarizing the results of the pediatric postmarket surveillance of a device is expected to be submitted to FDA. Once the final report has been submitted, the actual date on which the final report is submitted to FDA.''

The Agency considers the proposed list of required data elements for a pediatric postmarket surveillance of a device that is not a clinical trial to be the most inclusive set of data elements that could be expected to apply to all pediatric postmarket surveillances of a device that are not clinical trials, regardless of the design of the surveillance. The proposed required information would allow users to access records of a pediatric postmarket surveillance of a device that is not a clinical trial by searching using a number of relevant criteria, retrieve basic descriptive information about the surveillance, and find a point-of-contact for additional surveillance information.

We do not propose the submission of those data elements listed under section 402(j)(2)(A)(ii) of the PHS Act that are not expected to apply to all pediatric postmarket surveillances of a device that are not clinical trials. For example, Study Phase is relevant only to clinical trials involving drugs. The specific elements of Study Design (e.g., Interventional Study Model, Allocation, Masking, Single Arm Controlled?) would not apply to most studies that are not interventional clinical studies (i.e., clinical trials). Eligibility Criteria, Age, and Gender might not be defined specifically for the study population in a pediatric postmarket surveillance of a device that is not a clinical trial. Enrollment would not be relevant to a pediatric postmarket surveillance of a device that takes the form of a literature review. We expect that some information about the study design and relevant study population would be included in the brief summary of the pediatric postmarket surveillance of a device.

In addition, for pediatric postmarket surveillances of a device that are not clinical trials, we would recommend that the responsible party submit any other registration information data elements that are consistent with the surveillance design and are capable of being accepted by ClinicalTrials.gov. For example, for a pediatric postmarket surveillance of a device that takes the form of a prospective observational study, information such as the location(s) of the surveillance, its eligibility criteria, recruitment status, and outcome measures would also be relevant and should be submitted. We believe the public would be best served if additional descriptive information about these pediatric postmarket surveillances of devices were included in the data bank, but, given the lack of experience to date, we cannot at this time specify which additional information would be relevant to a particular type of pediatric postmarket surveillance of a device that is not a clinical trial. We invite public comments on alternative approaches to specifying the registration requirements for a pediatric postmarket surveillances of a device that is not a clinical trial, including specific information that should be required to be submitted for such a surveillance and approaches to help ensure that important information is not missing from the record when such information might not be relevant to all pediatric postmarket surveillances of a device that are not clinical trials.

(c) Data elements required to create expanded access records. Proposed § 11.28(c) describes the clinical trial information that must be submitted to ClinicalTrials.gov to register an

applicable drug clinical trial that studies an unapproved drug or unlicensed biological product that is available via an Expanded Access Program under section 561 of the FD&C Act to those who do not qualify for enrollment in a clinical trial. Under our proposal in § 11.28(c), the following set of data elements would be required to be submitted to ClinicalTrials.gov at the time of registration of such clinical trials: (1) Brief Title; (2) Official Title; (3) Brief Summary; (4) Study Type (which would be ''expanded access program'' for this type of record); (5) Primary Disease or Condition; (6) Intervention Name(s); (7) Other Intervention Name(s); (8) Intervention Description; (9) Intervention Type (which would be a drug, including biological products, for applicable clinical trials that are required to submit such information under the proposed part, but could be a device if clinical trial information is submitted voluntarily for an expanded access program for a device); (10) Eligibility Criteria, (11) Gender, (12) Age Limits, (13) Expanded Access Status; (14) Name of the Sponsor; (15) Responsible Party, by Official Title; (16) Contact Information; (17) Unique Protocol Identification Number; (18) Secondary IDs; (19) Food and Drug Administration IND Number; (20) Record Verification Date; and (21) Responsible Party Contact Information.

We consider the proposed set of data elements to be the most inclusive set of data elements that would be relevant to all expanded access programs (other than individual patient access), regardless of design, and would be helpful to users of ClinicalTrials.gov who wish to determine whether they might be eligible to receive treatment through the expanded access program and obtain additional information about such access. The proposed list is, in most part, a subset of the data elements that would be required to register an applicable clinical trial of a drug. The descriptions of the data elements generally parallel the definitions of the data elements in proposed § 11.10(b) that are required to be submitted when registering a clinical trial under proposed § 11.28(a) but have been modified to refer to expanded access programs rather than clinical trials and to be limited to expanded access programs for drugs and biologics. One data element that is not defined in proposed § 11.10(b) and would be required to be submitted only for expanded access records is the Expanded Access Status data element. It is defined in proposed § 11.28(c)(2)(iv) to mean ''[t]he status of availability of the investigational drug through the expanded access program.'' When submitting this data element, responsible parties would be required to select from the following limited set of options for describing the current status of availability of the investigational drug through the expanded access program: ''Available'' (expanded access is currently available), ''No longer available'' (expanded access was available previously but is not currently available and is not expected to be available in the future), ''Temporarily not available'' (expanded access was previously available, is not currently available, but is expected to be available in the future), and ''Approved for marketing'' (expanded access was available previously but is not currently available because the drug or device has been approved, licensed, or cleared by the Food and Drug Administration). No ''other'' option is proposed. These proposed options are consistent with those used in ClinicalTrials.gov prior to enactment of FDAAA [Ref. 2] and would provide patients and other users of ClinicalTrials.gov with what we believe is more valuable information about expanded access status than a simple ''yes'' or ''no'' indication. We invite comment on whether this list of options is sufficient to describe the status of an expanded access program for which information would be submitted to ClinicalTrials.gov under this proposed rule.

We note that, notwithstanding the foregoing, if some form of expanded access were offered to a medical device that is studied in an applicable clinical trial, such information could be submitted voluntarily under section 402(j)(4)(A) of the PHS Act to create an expanded access record for the device. Accordingly, even though the expanded access data elements are intended for expanded access programs for drugs, a responsible party who voluntarily submits information about an expanded access program for a device would be able to submit the IDE number that CDRH assigns to the expanded access program. We would require that a responsible party who voluntarily creates an expanded access record for a device expanded access program submit all of the data elements that are required for a drug expanded access program. In other words, an expanded access record may be created voluntarily, but it must be complete. In addition, we would require that an expanded access record that is submitted voluntarily must be updated following the same requirements that would apply to an expanded access record that is required to be submitted under this part. *See* proposed 11.64(b)(1(iv).

We propose to require the submission of information to create an Expanded Access record using the statutory authority in section 402(j)(2)(A)(iii) of the PHS Act, which allows the Secretary by regulation to modify the requirements for clinical trial registration information if the Secretary provides a rationale why such a modification ''improves and does not reduce such clinical trial information.'' Information about the availability of expanded access is a data element that a responsible party is required to submit under section 402(j)(2)(A)(ii)(II) of the PHS Act and thus meets the definition of ''clinical trial information'' as that term is used in section 402(j)(1)(A)(iv) of the PHS Act. We believe the additional data elements describing expanded access would improve and not reduce clinical trial information by providing users with more complete and consistent information about expanded access programs for drugs studied in applicable clinical trials than would be available pursuant to section 402(j)(A)(ii)(II)(gg) of the PHS Act alone. We further conclude that we have authority to require that the clinical trial information required under proposed § 11.28(c) be submitted by creating a separate expanded access record in ClinicalTrials.gov under section 402(j)(2)(B)(iv) of the PHS Act, as the expanded access record will ensure that the public may more easily use the data bank to determine whether there is expanded access to a drug and to compare different expanded access programs. In addition, this approach is consistent with the practice followed prior to enactment of FDAAA when those registering trials in compliance with FDAMA submitted expanded access information in the form of expanded access records at ClinicalTrials.gov. As discussed above in section IV.A.5 of this preamble, in the rare instance in which an expanded access program for a drug is controlled and meets all of the elements of an applicable drug clinical trial, the expanded access program must be registered as an applicable drug clinical trial.

We considered alternative approaches, such as requiring the responsible party to submit the name, phone number, and email address of a point-of-contact or Web site for information about the expanded access program for each clinical trial of a drug that has such a program. However, we believe that such an approach would not ensure that complete information is

available in a consistent form and would not allow users of ClinicalTrials.gov to as quickly and easily review eligibility criteria and the disease or condition for which expanded access is available. In addition, by including such information as part of clinical trial registration information, we can better ensure that the information is kept up-to-date because it would be subject to the updating requirements described in proposed § 11.64. We also believe that our proposal could reduce the burden a responsible party faces when providing information about expanded access. An alternative we considered was to require responsible parties to enter the additional data elements describing expanded access with every applicable clinical trial of a drug or biological product for which expanded access is available. Under our proposal, in situations in which multiple applicable clinical trials study the same drug that is available via the expanded access program, the expanded access record would be submitted only once, and thereafter, any responsible party could link the expanded access record to his or her clinical trial record(s) using the NCT number assigned to the expanded access record. As explained further in section IV.D.3 in this preamble, only that responsible party who registered the initial clinical trial that included the expanded access record would be responsible for updating the expanded access program information in the expanded access record.

As explained in section IV.B.4, in the discussion of the Availability of Expanded Access data element, the expanded access record generated in ClinicalTrials.gov pursuant to the submission of the data elements at proposed § 11.28(c) would be assigned its own NCT number and would be searchable and retrievable independent of the record(s) for the clinical trial(s) that study(ies) the drug or biological product to which expanded access is offered. To establish the link between the expanded access record and the clinical trial record(s), the responsible party(ies) for any applicable clinical trials of the drug available via expanded access would be required to include the NCT number that is assigned to the expanded access record as part of the registration information submitted for that clinical trial. The expanded access record could be linked in this fashion to several applicable clinical trials that study the drug or biological product that is available via the expanded access program.

We seek comment on the proposed approach.

5. By when will NIH post clinical trial information submitted under § 11.28?—§ 11.35.

Proposed § 11.35 describes the timelines by which NIH will post publicly on ClinicalTrials.gov the clinical trial information that is required to be submitted for registration of applicable drug clinical trials and applicable device clinical trials, respectively. Proposed § 11.35 takes into account the timelines described for posting registration information in section 402(j)(2)(D) of the PHS Act.

The timelines in proposed § 11.35 apply only to clinical trials that are required to register with ClinicalTrials.gov under 402(j)(2)(C) of the PHS Act. If a clinical trial is registered with ClinicalTrials.gov and appears to be a voluntary submission according to the approach specified in proposed § 11.22(b), we will post the registration information as soon as practicable after it has been submitted and reviewed as part of our quality review procedures.

(a) Applicable drug clinical trials. For applicable drug clinical trials, section 402(j)(2)(D)(i) of the PHS Act requires NIH to publicly post registration information not later than 30 days after it is submitted in accordance with section 402(j) of the PHS Act. Proposed § 11.35(a) implements this provision, stating that NIH will post publicly the registration information ''not later than 30 calendar days after the responsible party has submitted such information in accordance with § 11.24 of this part.''

(b) Applicable device clinical trials of devices that previously were approved or cleared. For applicable device clinical trials of devices that previously were approved or cleared by FDA for any indication, section 402(j)(2)(D)(ii)(II) of the PHS Act requires that registration information be posted ''not later than 30 days after'' results information is required to be posted. The Agency interprets section 402(j)(2)(D)(ii)(II) of the PHS Act as providing a deadline by which such registration information must be posted. In other words, the Agency considers the requirement to post registration information ''not later than 30 days after [results information] is required to be posted'' to be the last possible date on which it may post registration information.

The Agency believes that for applicable device clinical trials of devices that previously were approved or cleared it is permissible and appropriate to post registration information prior to the deadline. Posting this information prior to the deadline would be consistent with the objectives of expanding the registry and results data bank by rulemaking, facilitating enrollment in clinical trials and providing a mechanism to track subsequent progress of clinical trials. (See sections 402(j)(2)(A)(i) and (3)(D)(i) of the PHS Act.) Conversely, waiting to post registration information for applicable device clinical trials of devices that previously were approved or cleared until after results information is required to be posted would delay access to information about such clinical trials and would eliminate the possibility for the data bank to be used to facilitate enrollment in such trials and to allow the public to track such trials while they are ongoing.

The Agency proposes in § 11.35(b)(1) to post registration information for an applicable device clinical trial of a device that previously was approved or cleared ''not later than 30 calendar days after clinical trial results information is required to be posted in accordance with § 11.52 of this part.'' However, in light of the objectives of the data bank discussed above we intend, in practice, to post registration information for such applicable device clinical trials as soon as practicable after submission, but not later than 30 calendar days after clinical trial results information is required to be posted.

(c) Applicable device clinical trials of devices that have not been approved or cleared previously. Section 402(j)(2)(D)(ii)(I) of the PHS Act provides that for applicable device clinical trials of devices that have not previously been approved or cleared (i.e., unapproved or uncleared devices), registration information must be posted publicly not earlier than the date of approval or clearance of the device and not later than 30 days after such date. Proposed § 11.35(b)(2) reflects this statutory provision. In order to help us meet the posting deadline and identify the set of applicable device trials for which registration information needs to be posted after approval or clearance of a device, we have included a requirement in proposed § 11.64(b)(2) for the responsible party to update the U.S. FDA Approval, Licensure, or Clearance Status data element not later than 15 calendar days after a change in status has occurred. The responsible party would be required to update that data element for all applicable clinical trials that study the device that was approved or cleared.

(d) Exception to posted information. Section 402(j)(2)(A)(ii)(IV) of the PHS Act specifies that the Secretary ''may make publicly available *as necessary*'' (emphasis added) administrative data that are submitted as part of clinical

trial registration information. We interpret this provision as permitting the Secretary not to post certain administrative data in the data bank if the data are not considered necessary for understanding the clinical trial or for recruitment. As explained more fully in section IV.B.4(a) of this preamble, we do not believe it is necessary to make public the following administrative data and currently do not intend to post them publicly in ClinicalTrials.gov for any applicable clinical trials: (1) Food and Drug Administration IND or IDE Number and (2) Responsible Party Contact Information other than the name of the responsible party if the responsible party is an individual (as opposed to an entity). Note that Responsible Party, by Official Title, which is proposed in § 11.28(a)(3)(ii), is not considered an element of administrative data and will be publicly posted in the data bank as required by section 402(j)(2)(A)(ii)(III)(bb) of the PHS Act.

C. Results Submission—Subpart C

Proposed subpart C establishes requirements and procedures related to the submission of results information. In addressing what constitutes results information, proposed subpart C does not specify what results information must be collected during an applicable clinical trial or other clinical trial, but which elements of the collected data must be submitted and in what required format. Proposed Subpart C also specifies when NIH will post results information in ClinicalTrials.gov. Finally, proposed subpart C specifies the procedures that may be used to request a waiver of any applicable requirements for results submission.

1. Who must submit results information?—§ 11.40

Proposed § 11.40 requires that the responsible party for an applicable clinical trial specified in proposed § 11.42 submit results information for that clinical trial. This approach is consistent with section 401(j)(3)(E)(i) of the PHS Act.

2. For which applicable clinical trials must results information be submitted?—§ 11.42

Proposed § 11.42 identifies the applicable clinical trials for which results information must be submitted to ClinicalTrials.gov, according to this proposed rule unless the requirement is waived under proposed § 11.54. Pursuant to section 402(j)(3)(D)(ii)(I)of the PHS Act, we propose to require the submission of results information for specified: (1) Applicable clinical trials of drugs that are approved under section 505 of the FD&C Act or licensed under section 351 of the PHS Act; and (2) applicable clinical trials for devices that are cleared under section 510(k) of the FD&C Act or approved under section 515 or 520(m) of the FD&C Act. For reasons described in section III.C.5 of this preamble, we also propose to require the submission of results information for specified applicable clinical trials of drugs or devices that are not approved, licensed, or cleared for any indication (regardless of whether the sponsor seeks approval, licensure, or clearance). This proposal is consistent with the requirement in section 402(j)(3)(D)(ii)(II) of the PHS Act that the Secretary establish through regulation whether or not results information must be submitted for applicable clinical trials of drugs and devices that have not been approved, licensed, or cleared by FDA, whether or not approval, licensure, or clearance is sought.

In order to maintain consistency with the registration requirements proposed in this rule, the proposed requirements for results submission would apply to those applicable clinical trials that are required to be registered with ClinicalTrials.gov under the requirements of proposed § 11.22 and that meet the criteria under proposed § 11.42, unless a waiver were granted in accordance with proposed § 11.54. We note as described in section III.D of this preamble, responsible parties would not be required to submit results information under this proposed subpart if the completion date of the applicable clinical trial is prior to the effective date of this rule, except if any of the following situations applies: (1) The completion date is prior to the effective date of the rule, but results information is neither due under proposed § 11.44 nor submitted until on or after the effective date of the rule; or (2) the completion date is prior to the effective date of the rule, but secondary outcome measures are neither due under proposed § 11.44 nor submitted until on or after the effective date of the rule.

3. When must results information be submitted for applicable clinical trials subject to § 11.42–§ 11.44?

Proposed § 11.44 specifies the deadlines for submitting results information for applicable clinical trials. Subsection (a) specifies the standard submission deadlines for applicable clinical trials that are clinical trials. Subsections (b) and (c) specify procedures for delaying the standard submission deadlines when seeking initial approval or approval of a new use of a drug or device studied in an applicable clinical trial. Subsection (d) describes procedures for requesting a good-cause extension of the submission deadline. Subsection (e) establishes the timeline for submitting results of a pediatric postmarket surveillance of a device that is not a clinical trial.

(a) Standard submission deadlines. Proposed § 11.44(a) prescribes the standard deadlines for submitting results information for applicable clinical trials that are clinical trials subject to proposed § 11.42. This proposed deadline would apply to all applicable clinical trials for which the responsible party does not submit a certification to delay results submission, as permitted under proposed § 11.44(b) or (c), or for which the Director has not granted a good-cause extension of the results submission deadline pursuant to proposed § 11.44(e).

(1) In general. Proposed § 11.44(a)(1) specifies that, in general, the deadline for submitting results information for applicable clinical trial would be 1 year after the completion date of the clinical trial. Sections 402(j)(3)(E)(i)(I) and (II) of the PHS Act specify that results information is to be submitted not later than 1 year after the ''earlier of'' the estimated completion date or the actual completion date. Under proposed § 11.64(b)(1), however, we would require responsible parties to update the completion date not later than 30 calendar days after a change has occurred or after the clinical trial has reached its completion date. Therefore, the estimated completion date would be updated to reflect the actual completion date not later than 30 calendar days after the applicable clinical trial has reached its completion date and results would be due not later than 1 year after the actual completion date of the applicable clinical trial.

The 1 year deadline would apply to applicable clinical trials of drugs and devices, whether or not approved, licensed, or cleared, except as described in (2) and (3) below. Section 402(j)(3)(D)(iv)(III) of the PHS Act requires the Secretary to determine by regulation ''the date by which . . . clinical trial [results] information [for applicable clinical trials of unapproved, unlicensed, or uncleared products] shall be required to be submitted . . .'' As discussed further in section III.C.5 of this preamble, our proposal would apply the same general deadline for results submission to both applicable clinical trials of approved, licensed, or cleared products and applicable clinical trials of unapproved, unlicensed, or uncleared products in order to simplify

results submission procedures and provide consistency between the deadlines for applicable clinical trials, regardless of the approval status of the products under study. Applicable clinical trials of unapproved, unlicensed, or uncleared drugs and devices (and of approved, cleared, and licensed drugs and devices that are studied for a new use) may, however, qualify for delayed submission of results, as described in section IV.C.3(b) below.

Section 402(j)(3)(D)(iv)(I) of the PHS Act requires the Secretary to determine whether to increase the general deadline for results submission from 1 year to ''a period not to exceed 18 months'' after the earlier of the estimated or actual completion date. We solicited comment on this topic as part of the public meeting held in April 2009 but received few comments on this issue. Comments that supported a longer deadline cited concerns about applicable clinical trials for which data collection for secondary outcome measures and adverse events would continue beyond the completion date of the clinical trial. During the time that we have been operating the data bank, we have seen only few clinical trials in which this situation occurs. Rather than extending the general results submission deadline to as long as 18 months in order to accommodate what we believe would be a small number of such trials, we propose instead alternative methods for addressing such trials in proposed § 11.44(a)(2).

(2) Submitting results information following initial product approval, licensure, or clearance. Proposed § 11.44(a)(2) specifies the timeline for submitting results information for any applicable clinical trial of an FDA-regulated drug (including biological product) or device that is unapproved, unlicensed, or uncleared as of its completion date. It would require that results information as specified in proposed § 11.48(a) must be submitted for such trials by the earlier of 1 year after the completion date, or 30 calendar days after FDA approves, licenses, or clears the drug or device for any indication studied in the applicable clinical trial. This proposal is consistent with section 402(j)(3)(E)(iv) of the PHS Act.

(b) Delayed results submission with certification. Proposed §§ 11.44(b) and (c) establish procedures whereby responsible parties may delay submission of results information for a particular applicable clinical trial beyond the general deadline specified in proposed § 11.44(a)(1) (i.e., 1 year after the completion date).

(1) Seeking approval, licensure, or clearance of a new use for the drug or device. Consistent with section 402(j)(3)(E) (iii) and (v) of the PHS Act, we propose in § 11.44(b) to allow a delay in the submission of results information if the responsible party certifies that an applicable clinical trial meets the following criteria: (1) The drug (including biological product) or device studied in the applicable clinical trial previously has been approved, licensed, or cleared by FDA; (2) the sponsor of the applicable clinical trial is the manufacturer of the product; and (3) the manufacturer has filed, or will file within 1 year, an application seeking approval, licensure, or clearance of the use being studied in the applicable clinical trial (a use that is not included in the labeling of the approved, licensed, or cleared product). As proposed, this certification would be required to be submitted to ClinicalTrials.gov before the general results submission deadline specified in proposed § 11.44(a)(1), i.e., 1 year or less after the completion date. The record for the clinical trial would indicate that results submission has been delayed, but would not specify the particular reason for the delay. (See section IV.C.3 of this preamble).

In accordance with section 402(j)(3)(E)(v) of the PHS Act, once a certification has been submitted, proposed § 11.44(b)(2) would permit a delay in the submission of results information of up to two years after the date on which the certification is submitted, unless one of the following events occurs: (1) FDA approves, licenses, or clears the drug or device studied in the applicable clinical trial for the use studied in the clinical trial; (2) FDA issues a letter that ends the regulatory review cycle for the application or submission (e.g., a complete response letter, a not substantially equivalent letter, or a not approvable letter) but does not approve, license, or clear the product studied in applicable clinical trial for the use studied in the clinical trial; or (3) the manufacturer, which is also the sponsor of the applicable clinical trial, withdraws the application or premarket notification and does not resubmit it within 210 calendar days. In the event that any one of these ''triggering events'' occurs, the responsible party would be required to submit results information for the applicable clinical trial for which a certification had been submitted under proposed § 11.44(b)(1) not later than 30 calendar days after the earliest of the triggering events occurred, consistent with section 402(j)(3)(E)(v)(I).

If the responsible party for an applicable trial for which a new-use certification has been submitted is not the sponsor/manufacturer of the drug (including biological product) or device studied in the clinical trial, the sponsor/manufacturer may need to notify the responsible party of the occurrence of these triggering events in order to help ensure that the responsible party is aware that results submission is required. As discussed in section IV.A.2 of this preamble, the sponsor may designate a principal investigator as responsible party under proposed § 11.4 only if, among other things, the principal investigator ''has the ability to meet all of the requirements for submitting and updating clinical trial information as specified in this part.'' Accordingly, a responsible party who is not the sponsor will only be able to comply with the results submission requirements subsequent to a certification under sections 402(j)(3)(E)(iii) and (v) of the PHS Act, if notified by the sponsor when one of these triggering events occurs. In a situation in which a sponsor is not willing or able to provide the principal investigator with this information, the conditions for designation under proposed § 11.4 cannot be met.

In addition, consistent with section 402(j)(3)(E)(v)(II) of the PHS Act, if a manufacturer makes a certification to delay submission of results information because the manufacturer is seeking or will seek within 1 year approval of a new use for a drug or device, the responsible party shall make such a certification ''with respect to each applicable clinical trial that is required to be submitted in an application or report for licensure, approval, or clearance'' of the use studied in the clinical trial. Proposed § 11.44(b)(3) implements this provision. For purposes of this requirement, we interpret ''manufacturer'' to mean ''manufacturer/sponsor who is the responsible party'' because section 402(j)(3)(E)(v) of PHS Act applies only when the manufacturer is the sponsor of the applicable clinical trial, and under section 402(j)(3)(E)(iii) of the PHS Act, it is the responsible party who must submit the certification for delayed submission of clinical trial results information.

(2) Seeking initial approval, licensure, or clearance for the drug or device. Proposed requirements for delayed submission of results information with certification when seeking initial approval, licensure, or clearance of a drug or device are described in proposed § 11.44(c). As discussed above in section III.C.5 of this preamble, this proposal reflects our efforts to adhere to

the statutory requirement that, when proposing to require the submission of results information for trials of unapproved, unlicensed, or uncleared products, we take into account the certification process in section 402(j)(3)(E)(iii) of the PHS Act ''when approval, licensure, or clearance is sought,'' and that we determine ''whether there should be a delay of submission when approval, licensure or clearance will not be sought.'' See section 402(j)(3)(D)(iv)(III) of the PHS Act.

We propose in § 11.44(c) that submission of results information may be delayed if the responsible party certifies that the following criteria apply: (1) The drug (including biological product) or device studied in the applicable clinical trial previously was not approved, licensed, or cleared by FDA for any use before the completion date of the clinical trial; and (2) the sponsor of the applicable clinical trial intends to continue with product development and is seeking, or may at a future date seek, FDA approval, licensure, or clearance of the product under study. As proposed, this certification would be required to be submitted to ClinicalTrials.gov before the general results submission deadline specified in proposed § 11.44(a)(1), i.e., 1 year or less after the completion date.

The intent of this certification is to permit delayed results submission only if the sponsor of the applicable clinical trial intends to continue with product development of the drug (including biological product) or device under study, such that there is an expectation that marketing approval or clearance will be sought. We do not believe that results submission should be delayed for applicable clinical trials of products that the sponsor has no intention of marketing or for which product development has been abandoned.

Hence, our proposal would permit delayed submission of results information only if the responsible party certifies that the sponsor of the applicable clinical trial is continuing to study the product with an expectation of seeking future marketing approval, licensure, or clearance. We recognize that it may be difficult for the sponsor of the applicable clinical trial to know early on in the product development process whether it will seek approval, licensure, or clearance for a product studied in an applicable clinical trial, but we would, in general, view further development of a product through subsequent clinical trials as an indication that the product development process is continuing and may lead to seeking initial approval, licensure, or clearance. When the responsible party is not the sponsor of the applicable clinical trial and wishes to delay results submission, we would expect the responsible party to obtain such information from the sponsor before submitting a certification, in order to help ensure the truthfulness of the certification.

Under our proposal, submission of a certification would delay the deadline for submitting results for the applicable clinical trial by up to two years from the date on which the certification is submitted to ClinicalTrials.gov. However, in the event that FDA approves, licenses, or clears the drug or device studied in the applicable clinical trial for any indication that is studied in the clinical trial within this two-year period, the responsible party would be required to submit results information not later than 30 calendar days after such approval, licensure, or clearance. Similarly, if the sponsor withdraws the application or premarket notification without resubmission for 210 calendar days during this two-year period, the responsible party would be required to submit results information not later than 30 calendar days after such date. The agency believes that this latter situation represents a significant enough interruption to product development to trigger the submission of results information.

We note that, unlike delayed results submission with certification that the sponsor of the applicable clinical trial is seeking approval, licensure, or clearance of a new use, we do not propose to require the submission of results 30 days after FDA issues a letter not approving, licensing, or clearing the product under study because we do not think that the issuance of such a letter necessarily indicates abandonment of product development. For the reasons set forth above in ''(1) ''Seeking approval, licensure, or clearance of a new use for the drug or device[,]'' a responsible party who is not the sponsor (i.e., a responsible party who is a principal investigator) will be able to comply with the results submission requirements subsequent to a certification under sections 402(j)(3)(E)(iii) and (iv) of the PHS Act, only if notified by the sponsor when one of the triggering event occurs. In a situation where the sponsor is not willing or able to provide the principal investigator with this information, then the conditions for designation under proposed § 11.4 cannot be met, and/or the responsible party will not be eligible to delay results submission.

(3) Two-Year Limitation of Delay. With regard to the maximum delay pursuant to a certification submitted under section 402(j)(3)(E)(iii) of the PHS Act, the agency expects that in most situations a delay of an additional two years beyond the date the certification is submitted (i.e., up to three years after the completion date of the clinical trial, if the certification is submitted 1 year after the completion date) provides sufficient time for the sponsor of the applicable clinical trial to protect its competitive advantage, a concern expressed in public comments. Within this time frame, a sponsor would likely make a decision about whether to halt product development, initiate another clinical trial (e.g., a phase 3 clinical trial to follow a phase 2 clinical trial), or submit a marketing application or premarket notification to FDA. Subsequent trials would most likely be required to register at ClinicalTrials.gov and, for applicable drug clinical trials, the clinical trial registration information for those subsequent trials would be posted publicly in the data bank, thereby providing some information to competitors about the outcome of previous trials and the objectives of future trials. As discussed further in Section III.C.5 of this preamble, we believe any competitive disadvantage caused by the disclosure of summary results information three years or more after the completion date of the trial would be limited and outweighed by the public health benefits of making such information publicly available. We invite public comment on this approach.

For applicable clinical trials that meet the criteria for delayed results submission with certification—whether seeking initial approval, licensure, or clearance or seeking approval, licensure, or clearance of a new use—measuring the maximum delay of two years from the date on which the certification is submitted may result in responsible parties submitting certifications as close as possible to the general results submission deadline under proposed § 11.44(a)(1) (i.e., 1 year after the completion date). Submitting a certification just before the general results submission deadline would postpone results submission until as late as three years after the completion date of the clinical trial, while submitting a certification on the completion date of the clinical trial would extend the results submission deadline only as long as two years beyond the completion date. We believe that users of ClinicalTrials.gov would benefit from knowing as early as possible that results submission for an applicable clinical trial of interest

would be delayed. Until a certification is submitted, users may expect that results will be submitted not later than 1 year after the completion date. If a certification were submitted soon after the completion date, the clinical trial record could be updated at that time to indicate that results submission would be delayed, and users could adjust their expectations accordingly.

The statute does not appear to permit us to change the timeline for results submission when a responsible party submits a certification when seeking approval of a new use for the drug or device under section 402(j)(3)(E)(v) of the PHS Act and proposed § 11.44(b). For delayed submission of results when seeking initial approval, licensure, or clearance, however, the statute offers greater flexibility in establishing the timeline: Section 402(j)(3)(D)(iv)(III) of the PHS Act expressly authorizes the Secretary to establish the date by which clinical trial information for applicable clinical trials of unapproved products must be submitted to ClinicalTrials.gov. We considered establishing the maximum available delay with certification when seeking initial approval, licensure, or clearance to be three years from the completion date of the applicable clinical trial, regardless of when during the one-year period following the completion date the certification is submitted. Such a provision would accomplish the same objective as the statutory provision for delayed submission when seeking approval, licensure, or clearance of a new use by allowing responsible parties to delay results submission by as long as three years beyond the completion date of a clinical trial, without creating a disincentive to submit the certification early. We did not include this provision in this proposed rule so that we could keep the same maximum delay for results submission whether seeking initial approval, licensure, or clearance or seeking approval, licensure, or clearance of a new use. We invite public comments on the advantages and disadvantages of establishing maximum different timelines for results submission under the two delayed-results-with- certification provisions. We also invite public comment on alternative approaches we could take to encourage early submission of certifications in a way that is consistent with the statutory requirement for seeking approval, licensure, or clearance of a new use, without causing a responsible party to have to submit results information earlier than the latest deadline they could have under the statute.

We note that the maximum delay of two years pursuant to a certification submitted under section 402(j)(3)(E)(iii) of the PHS Act applies to all primary outcomes and any secondary outcomes for which the final subject was examined or received an intervention for the purposes of final data collection by the completion date. In the event that data collection for any secondary outcome measure(s) will not be completed as of the completion date, clinical trial results information for such secondary outcome measure(s) shall be due under proposed § 11.44(b) and (c) by the later of: (1) ''1 year after the date on which the final subject is examined or receives an intervention for the purposes of final collection of data for such secondary outcome measure(s), whether the applicable clinical trial was concluded according to the pre-specified protocol or was terminated;'' or (2) ''the date on which the primary outcomes are due pursuant to . . . [proposed §§ 11.44(b) or (c).''

(c) Explanation of ''initial approval,'' ''initial clearance,'' and approval or clearance of a ''new use.'' For purposes of proposed §§ 11.44(b) and (c), we interpret the term ''drug'' in sections 402(j)(3)(E)(iv) and 402(j)(3)(E)(v) of the PHS Act to mean ''drug product'' or ''biological product,'' referring to a finished product that is approved or licensed for marketing, and not to the active ingredient or active moiety in such a product. We conclude that this is the most appropriate interpretation of the statutory term and that this interpretation is consistent with the statutory intent to draw a distinction between applicable drug clinical trials that are ''completed before the drug is initially approved'' (See section 402(j)(3)(E)(iv) of the PHS Act) and those pertaining to uses that are ''not included in the labeling of the approved drug'' (See section 402(j)(3)(E)(v) of the PHS Act). Accordingly, ''initial approval'' pertains to the approval or licensure of an original NDA, abbreviated new drug application (ANDA) or BLA, and ''new use'' pertains to the approval or licensure of a supplemental NDA, ANDA, or BLA for an additional indication for that particular drug product or biological product. Similarly, we interpret ''initial approval'' of a device under sections 515 or 520(m) of the FD&C Act to pertain to the approval of an original premarket approval application (PMA) or humanitarian device exemption application (HDE) and ''new use'' to pertain to the approval of a supplemental PMA for an additional indication for that particular device.

In addition, for purposes of proposed § 11.44(c), the first 510(k) cleared for a particular device type would be considered ''initial clearance'' of the device. For example, when a device is reclassified from Class III to Class II, then the first 510(k) that is cleared as having demonstrated substantial equivalence to the reclassified device would be considered initial clearance of the device. Consequently, for purposes of proposed § 11.44(b), all other 510(k)s cleared for a device type other than the first one, would be considered clearance of a new use.

We recognize that in some cases a responsible party may not know whether a particular applicable clinical trial will be used to support an original NDA, ANDA, BLA, PMA, or HDE as opposed to a supplemental NDA, ANDA, BLA, PMA, or HDE, or whether a clinical trial will be used to support a 510(k) seeking initial clearance of a device as opposed to a 510(k) seeking clearance of a new use. Responsible parties should use their best judgment based on information available at the time of certification in order to determine which type of certification is appropriate. We solicit comments on whether these are appropriate interpretations and distinctions for purposes of proposed §§ 11.44(b) and (c).

(d) Submitting partial results. Proposed § 11.44(d) specifies procedures for submitting results when required results information, as specified in proposed § 11.48, has not been collected for all secondary outcome measures by the date on which results information is due. Under the definition of completion date in proposed § 11.10(a), whether or not a clinical trial is completed is determined by the status of data collection for solely the primary outcome measure(s). An applicable clinical trial may therefore still be collecting data for the secondary outcome measure(s) after it has reached its completion date.

In this situation, the responsible party would be required to submit results information for the primary outcome measure(s) by the required due date specified in proposed § 11.44(a), (b), or (c), as applicable. Under proposed § 11.44(d)(i). If a certification to delay results submission has not been submitted under proposed § 11.44(b) or (c), results for each remaining secondary outcome measure would be due not later than 1 year after the date on which the final subject is examined or receives an intervention for the purposes of final collection of data for that secondary outcome measure, whether the clinical trial was concluded according to the

pre-specified protocol or was terminated. If the responsible party has submitted a certification to delay results submission under proposed § 11.44(b) or (c), results of the secondary outcome measures could be submitted by the later of the date specified proposed § 11.44(d)(i) or the date on which the primary outcome measures would be required to be submitted. We note that in either situation, if data collection for a secondary outcome measure is completed as of the completion date, results information for that secondary outcome measure would be required to be submitted on the same date as the primary outcome measure(s).

With respect to adverse event information (which is considered to be part of clinical trial results information described under proposed § 11.48), a responsible party would be required to submit information summarizing serious and frequent adverse events recorded to-date each time results information for a secondary outcome is submitted, until all the adverse event information required by this part has been submitted. We believe that this approach provides a better mechanism for handling submission of adverse event information than extending the general results submission deadline for all applicable clinical trials up to 18 months after the completion date. It would ensure that key results information for primary outcome measures is submitted to ClinicalTrials.gov within 1 year of the completion date, while allowing subsequent data collection to continue as planned.

We recognize that this approach may not be suitable for all applicable clinical trials for which data collection for secondary outcome measures extends more than 1 year beyond the completion date. In some circumstances, submitting results information for the primary outcomes not later than 1 year after the completion date might compromise the scientific integrity of the applicable clinical trial, for example, by requiring the applicable clinical trial to be unblinded before all data for the secondary outcome measures are collected. In those circumstances, we would expect a responsible party to seek a good-cause extension of the results submission deadline in proposed § 11.44(a)(1), following the procedures specified in proposed § 11.44(e).

We clarify in proposed § 11.44(d)(2) the way to handle results submission if results related to the primary outcome(s) were submitted prior to the effective date of the rule, but results data for the secondary outcome(s) are required to be submitted after the effective date. In such cases the responsible party would be required to provide results information for all primary and secondary outcome(s) as specified in § 11.48 of this proposed rule. We believe that consistent data must be provided for all outcome measures in a single clinical trial and therefore would apply the requirements of proposed § 11.48 to the clinical trial as a whole.

(e) Requesting a good-cause extension of the results submission deadline. Proposed § 11.44(e) outlines procedures for requesting good-cause extensions of the deadline for submitting results information. Section 402(j)(3)(E)(vi) of the PHS Act authorizes the Director to ''provide an extension of the deadline for submission of clinical trial [results] information . . . if the responsible party for the trial submits to the Director a written request that demonstrates good cause for the extension and provides an estimate of the date on which the information will be submitted.'' We interpret this authority as allowing the Director to grant an extension of any results submission deadline that may be in effect for a given applicable clinical trial, e.g., the general 12-month results submission deadline; a delayed submission deadline established by the submission of an appropriate certification under section 402(j)(3)(E)(iii) of the PHS Act; or an extended deadline established by a previously-granted good-cause extension. As for the latter, section 402(j)(3)(E)(vi) of the PHS Act explicitly allows the Director to ''grant more than one [good-cause] extension for a clinical trial.'' For a pediatric postmarket surveillance of a device that is not a clinical trial, the agency also proposes to allow more than one good-cause extension for such a surveillance. Good-cause extensions apply only in the context of applicable clinical trials subject to the results submission requirements of section 402(j)(3) of the PHS Act because the good-cause extension provision specifically refers to results submission under 402(j)(3)(E)(i) of the PHS Act. Accordingly, good-cause extensions do not apply to clinical trial results that are submitted under section 402(j)(4)(A) of the PHS Act, i.e., voluntarily submitted trials (see proposed rule § 11.60(a)(2)(i)) and triggered trials (see § 11.60(a)(2)(iii) of this proposed rule).

Section 402(j)(3)(E)(vi) of the PHS Act does not define ''good cause.'' Similarly, this proposed rule does not contain specific proposals for determining which situations will and will not be considered good cause for an extension. Instead we intend to develop guidance (which would be subject to public comment) as the agency gains more experience with extension requests and communicate with the regulated community via other channels, including the ClinicalTrials.gov Web site. In order to assist responsible parties who are considering submitting a good-cause extension request, we intend to prepare, update periodically, and post on ClinicalTrials.gov a list of reasons that the agency generally will consider to be ''good cause'' and not ''good cause'' for granting an extension under section 402(j)(3)(E)(vi) of the PHS Act and proposed § 11.44(e). The list would not necessarily be an exhaustive list of reasons for which applicable clinical trials have or have not been granted an extension, but would contain those reasons that we believe would serve as useful examples for responsible parties of other applicable clinical trials. All good-cause extension requests would be considered on a case-by-case basis, and any generalizable conclusions that can be drawn from the granting or denial of a request may be added to the list of good causes and not-good causes for granting extensions.

In general, we believe that there are likely to be only a few situations that would constitute good cause under section 402(j)(3)(E)(vi) of the PHS Act and proposed § 11.44(e). To-date, we have identified only two situations that we believe would constitute good cause, as follows:

(1) The need to preserve the scientific integrity of an applicable clinical trial for which data collection is ongoing. This would include situations in which the submission of results information for the primary outcome(s) of an applicable clinical trial would impair or otherwise bias the ongoing collection, analysis, and/or interpretation of data for secondary outcome(s). We recognize that permitting an extension in such circumstances could provide an incentive for someone wishing to delay results submission to add to their applicable clinical trial a secondary outcome measure with a very long data collection time frame, even if the outcome measure has limited significance or relevance to the clinical trial. Because protocols are typically revised by outside entities (e.g., human subjects protection review boards), one way to protect against such behavior is to ensure that the secondary outcome measures are pre-specified in the protocol or statistical analysis plan. Accordingly, in order to demonstrate good cause, we believe that an extension should be granted only in those situations in which it can be demonstrated that the data collection for the secondary outcome(s) of interest

extends more than 1 year beyond the completion date, that the secondary outcome(s) is pre-specified in the protocol or statistical analysis plan (consistent with the definition of secondary outcomes in this proposed part), and the planned analysis of the outcome measure is also described in the protocol or statistical analysis plan. The responsible party could provide this information either by voluntarily submitting copies of the protocol or statistical analysis plan with the good-cause extension request or describing them in the extension request itself.

(2) Emergencies that prevent timely submission of clinical trial results information. This would include situations in which one or more data collection sites are affected by natural disasters or other catastrophes outside the responsible party's or sponsor's control. In such cases we generally would expect to grant the responsible party an initial extension of up to 6 months, after which time additional extensions could be granted, as necessary. We generally would not consider events that might reasonably have been avoided or anticipated through standard contingency planning, e.g., transition planning for key staff members who leave an organization, to constitute good cause for an extension under section 402(j)(3)(E)(vi) of the PHS Act or proposed § 11.44(e).

The following non-exhaustive list enumerates scenarios that we generally do not believe ordinarily would constitute good cause:

- Pending publication. The ICMJE has asserted that results submission to ClinicalTrials.gov in compliance with section 402(j) of the PHS Act will not be considered ''prior publication'' and would not preclude future publication [Ref. 10].
- Delay in data analysis for unspecified causes. A general statement that provides no specific reason for a delay in data analysis, e.g., ''data could not be analyzed fully within 12 months,'' would not be considered to have demonstrated good cause.

If the estimated completion date displayed in the applicable clinical trial record is earlier than the actual (or current estimated) completion date, a responsible party must update the estimated completion date in the clinical trial record to reflect the actual (or revised estimated) completion date within 30 calendar days, as required by 11.64(b)(1)(viii) and should not request an extension based on the outdated completion date posted in the data bank. The fact that the responsible party has updated the completion date will be reflected in ClinicalTrials.gov, consistent with the handling of all updates under proposed § 11.64.

We invite public comment on these specific situations and on more general criteria that could be used to determine what constitutes good cause for an extension.

Proposed § 11.44(e)(1) outlines procedures for submitting a good-cause extension request. It indicates that extension requests must be submitted to NIH via ClinicalTrials.gov prior to the date on which results information would otherwise be due in accordance with the results submission deadlines established in proposed § 11.44(a), or § 11.44(b), or § 11.44(c), if the relevant certification has been submitted. The proposed process for submission of extension requests calls for direct electronic submission to ClinicalTrials.gov at *http://prsinfo.clinicaltrials.gov/.* Consistent with section 402(j)(3)(E)(vi) of the PHS Act, our proposal would require an extension request to include a description of the reason(s) why results information cannot be provided according to the applicable deadline and an estimated date on which results information will be submitted. Requests missing either piece of information would be considered incomplete and the responsible party would be notified that the request would not be considered by the agency until missing information is provided. The submitted extension request would be reviewed by an NIH official designated by the Director.

Proposed § 11.44(e)(2) specifies that a response to the good-cause extension request would be communicated electronically to the responsible party, providing notice as to whether or not the requested extension has been granted. This communication would take place via ClinicalTrials.gov. As indicated, if a request were granted, a revised deadline for results submission would be communicated in the notice, taking into account the particulars of the request. We note that the agency may grant a deadline that is earlier than that requested by the responsible party in the good-cause extension request. If a request were denied, the deadline for submitting results would be the later of the original submission deadline (e.g., 1 year after the completion date or the delayed submission deadline if a certification has been filed under subparts (b) or (c)) or 15 calendar days after the date the electronic notice of the denial of the request is sent to the responsible party.

Proposed § 11.44(e)(3) establishes an appeals process that would permit a responsible party a single opportunity to appeal the decision of the agency to deny an extension request or the deadline specified in a granted extension request. An appeals process was a feature that was requested at the public meeting in April 2009 (see, Ref. 1). Under proposed § 11.44(e)(3), a responsible party who appeals a denied extension request must submit the appeal in letter form to the Director not later than 15 calendar days after the date on which electronic notification of grant or denial of the request was sent to the responsible party.'' The appeal must explain why, in the view of the responsible party, the initial decision to deny an extension request or to grant an extension request with a shorter deadline than requested by the responsible party should be overturned or revised, e.g., by providing further elaboration of the grounds for the request or by highlighting factors that justify an extension. Generally, new information should not be submitted upon appeal, unless such information was not available at the time of the initial request. The submitted appeal will be considered by the Director.

If an appeal is granted, a revised deadline for results submission would be set by the Director, based on the particulars of the request, and provided to the responsible party in an electronic notification. If the appeal of a denied extension request is denied, the deadline for submitting results would be the later of the original submission deadline or 15 calendar days after the electronic notification of the denial of the appeal is sent to the responsible party. If the appeal of an extension request that was granted with a shorter deadline than was originally requested is denied, the deadline for submitting results would be the later of the deadline specified in the notification granting the extension request or 15 calendar days after the electronic notification of the denial of the appeal is sent to the responsible party.

(f) Posting of information about certifications for delayed submission and about good-cause extensions. We believe that ClinicalTrials.gov should indicate when the results submission deadline for a particular applicable clinical trial has been postponed because an extension request has been granted or the responsible party has submitted a certification for delayed submission. Without such an indication, users who view a clinical trial record that contains no results information more than 1 year after the completion date might be led to believe, incorrectly, that the responsible party has not complied with the results submission requirements of section 402(j)(3)(E) of

the PHS Act or this proposed rule, or that the agency has failed to post such information.

We believe that there would be value in posting information about the specific mechanism that has been used to delay the submission of clinical trial results information, i.e., a certification under proposed § 11.44(c) seeking initial approval, licensure, or clearance; a certification under proposed § 11.44(b) seeking approval, licensure, or clearance of a new use; or a good-cause extension under proposed § 11.44(e). Doing so would provide a mechanism to track the progress of clinical trials by informing users why clinical trial results information is not yet publicly available.

However, we recognize that the public posting of information about the specific mechanism used to delay results submission could result in the posting of information that might in some circumstances be considered confidential. For example, the fact that a responsible party had submitted a certification under proposed § 11.44(b) would indicate that the sponsor or manufacturer had submitted or was planning to submit within 1 year a marketing application or premarket notification to FDA for a new use of a drug or device that was studied in the applicable clinical trial. Such certification could be submitted to ClinicalTrials.gov prior to any public statement by the sponsor or manufacturer about its plans to apply for a new use. Similarly, the reasons underlying a request for a good-cause extension might contain details about the applicable clinical trial that previously have not been made public.

Our proposed approach attempts to balance the desire to indicate that the submission of clinical trial results information has been postponed for reasons that are permitted by statute and the need to avoid disclosure of confidential information. In order to avoid putting responsible parties in a position where they must agree to the release of information that would otherwise be considered confidential in order to delay results submission in accordance with a mechanism specified in section 402(j) of the PHS Act and this proposed part, we would post only minimal information about delayed results submissions in these circumstances. If a responsible party delays results submission via certification or is granted a good-cause extension of the deadline for submitting clinical trial results information, we propose to indicate in the clinical trial record only that results submission has been delayed. We would not indicate which mechanism was used to delay submission or the reason for which an extension may have been granted for a particular applicable clinical trial. In order to provide responsible parties with insight into the general types of reasons that have and have not been considered to constitute good cause for an extension, we propose to post and update periodically on the ClinicalTrials.gov Web site a generalized list of reasons for which extensions have and have not been granted. The listing would not indicate which applicable clinical trials have been granted or denied extensions based on the listed reason(s), and we would attempt to remove from the list any information that might allow a user to identify a specific applicable clinical trial.

We invite public comments on our proposed approach and whether more specific information could be provided about extensions and certifications for an individual applicable clinical trial (e.g., whether submission was delayed via extension or certification, and, if so, which type of certification) without releasing confidential information, what types of certification and extension information responsible parties would consider confidential, and alternative approaches that we could take that would provide more information to the public about the reasons for delayed submissions of clinical trial results information. We specifically invite comments on the advantages and disadvantages of providing more specific information about extension requests, e.g., that a request has been submitted for a clinical trial, the specific reason for the extension request, the responsible party's estimate of the date on which clinical trial results information could be submitted, whether or not the request was subsequently granted or denied, whether a denial has been appealed, and whether the appeal was granted or denied. Making such information available in ClinicalTrials.gov would further increase transparency into agency decisions and would provide an alternative means of informing interested parties about the types of situations that we consider good cause for an extension. We additionally invite public comment on whether extension requests could be submitted without containing any information that would be considered confidential and thus not suitable for release to the public.

(g) Results submission deadline for a pediatric postmarket surveillance of a device that is not a clinical trial. We recognize that the proposed deadlines for submitting clinical trial results information under proposed §§ 11.44(a)–(d) are not well adapted to a pediatric postmarket surveillance of a device that is not a clinical trial. Such surveillances generally do not have a completion date that can be easily measured by the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome. However, these surveillances will have a date on which a final report must be sent to FDA, as specified in the approved postmarket surveillance plan. Hence for a pediatric postmarket surveillance of a device that is not a clinical trial, we propose in § 11.44(e) that results information be submitted not later than 30 calendar days after the date that the final report is submitted to FDA. We believe that 30 days is sufficient additional time to allow the responsible party to format data as required by this part and submit it to ClinicalTrials.gov.

4. What constitutes results information?—§ 11.48

Proposed § 11.48 specifies procedures for submitting results information for an applicable clinical trial. Proposed § 11.48(a) specifies the general requirements that would apply to an applicable clinical trial other than a pediatric postmarket surveillance of a device that is not a clinical trial. Proposed § 11.48(b) describes the requirements for a pediatric postmarket surveillance of a device that is not a clinical trial.

In specifying the results information that must be submitted for a clinical trial proposed § 11.48(a) separates the data elements into the following general categories of information: (1) Participant flow, (2) demographic and baseline characteristics of the study population; (3) outcomes and statistical analyses; (4) adverse event information; (5) administrative information; and (6) additional results information for applicable device clinical trials of unapproved or uncleared devices. Note that whenever possible ClinicalTrials.gov will use information that was submitted during registration to pre-populate column and row names of the tables of information that required as part of results submission. Doing so would reduce the data entry burden on responsible parties and minimize the possibility of clerical errors. However, in all cases, the responsible party would be required to revise the information, as needed, so that the results information appropriately and accurately reflects the way data were collected and analyzed in the clinical trial. Each of the categories of results information that is required to

be submitted is addressed, in turn, below.

(a) Participant flow: As part of the requirements related to the demographic and baseline characteristics of the patient sample, section 402(j)(3)(C)(i) of the PHS Act specifies that a responsible party must submit ''[a] table of . . . data collected overall and for each arm of the clinical trial to describe the patients who participated in the clinical trial, including the number of patients who dropped out of the clinical trial and the number of patients excluded from the analysis, if any.'' We consider this information to be part of what we call ''participant flow.'' Participant flow refers to information, organized by arm of the clinical trial that documents the progression of human subjects through the clinical trial.

Consistent with section 402(j)(3)(C)(i) of the PHS Act and pursuant to our authority under section 402(j)(3)(D)(iii)(IV) of the PHS Act, we propose in § 11.48(a)(1) to require the submission of the following participant flow information: (1) Participant Flow Arm Information, consisting of ''[a] brief description of each arm used for describing the flow of participants through the clinical trial, including a descriptive title used to identify each arm[;]'' (2) Pre-assignment Information, which consists of ''[a] description of any significant events affecting the number of human subjects enrolled in the clinical trial but not assigned to an arm, if any[,]'' and (3) Participant Data, which is ''[t]he number of human subjects that started, and completed the clinical trial, by arm.'' This information permits the construction of a table that shows the flow of participants through the clinical trial.

In our proposed approach, information about the number of participants excluded from the analysis is not contained within participant flow, but would be submitted as part of the information about outcome measures, described below. We propose this approach because the number of participants excluded from analysis generally depends on the particular outcome measure being analyzed. A participant who drops out midway through a clinical trial, for example, may be included in the analysis of one outcome measure for which data collection was completed early in the study, but excluded from the analysis of another outcome measure for which data collection occurred (or continued) after the drop out. Hence, the aggregate number of participants excluded from the analysis could not generally be calculated by arm and the information by outcome measure would give a more accurate representation of the flow of human subjects through the clinical trial.

We intend to continue to provide responsible parties with a means of providing, on a voluntary basis, additional details about participant flow in a manner consistent with CONSORT guidelines [Ref. 24]. This information would consist of details about the flow of participants through different periods or milestones that might have been defined for a clinical trial and the reason(s) why participants did not complete the clinical trial or reach a particular milestone. Clinical trials often proceed through multiple periods (e.g., wash-out, consecutive cycles of the intervention), and having information about the participant flow in each period and reasons why participants did not complete the clinical trial or reach a particular milestone, if applicable, could improve users' understanding of the clinical trial data. Because clinical trials vary considerably in their design and may or may not include specific periods or milestones, there are no generally accepted approaches for submitting such information; nor is there consensus on how best to classify reasons for non-completion using categories that are comprehensive and not overlapping. Therefore, we do not propose a requirement to submit such information in this proposed rule; instead, we would allow such information to be submitted voluntarily by the responsible party. We have built into ClinicalTrials.gov the capability to accept such information, and we expect that continued experience with the voluntary submission of such information and continued efforts by the clinical trial research community may, over time, lead to the development of more widely accepted approaches to organize such information. We welcome public comment on the value of providing such additional information in ClinicalTrials.gov and on approaches for collecting it.

(b) Demographic and baseline characteristics: Section 402(j)(3)(C)(i) of the PHS Act requires submission of the following results information: ''A table of the demographic and baseline data collected overall and for each arm of the clinical trial to describe the patients who participated in the clinical trial . . .''

ClinicalTrials.gov provides pre-formatted rows that enable responsible parties to submit common demographic characteristics, including age, gender, race, ethnicity, and region of enrollment (with countries and geographic regions, such as Europe, Middle East, South America, listed on a pull-down menu), by arm or comparison group and overall for the clinical trial. Race and ethnicity data are submitted in accordance with the classification system of the Office of Management and Budget (OMB) (See 62 FR 58782, Oct. 30, 1997). We do not propose to require the submission of information describing all of these demographic characteristics because they may not all be collected as part of a particular clinical trial, and we do not wish to impose requirements on the data that must be collected during a clinical trial. Instead, in § 11.48(a)(2)(iii), we propose as a minimum requirement that responsible parties submit information describing the age and gender of the human subjects enrolled in the clinical trial. Age information can be provided as either a continuous variable (e.g., average age is 52 years) along with a measure of dispersion (e.g., standard deviation is 4.5 years) or a categorical variable (e.g., pediatrics, adults, seniors). Such information is generally collected in clinical trials and can be expected to be available for applicable clinical trials.

In addition, ClinicalTrials.gov accommodates the submission of information to describe an unlimited number of customized demographic and baseline characteristics. In general, we cannot specify in advance which other demographic and baseline characteristics must be provided for a particular clinical trial. Only those conducting the clinical trial will know which characteristics are important for their clinical trial and which actually were collected. We do believe it is important, however, that demographic and baseline measures be provided for any characteristic that is used in assessing outcome measures. For example, if an outcome measure compares a subject's blood pressure after 6 weeks of treatment with a particular intervention, we believe the baseline measure of blood pressure must be submitted. Similarly, if a clinical trial includes a statistical analysis that uses baseline data as part of the calculation (e.g., a regression analysis) we believe it is necessary to submit the relevant baseline data. The use of this baseline data in analyzing the outcome measure indicates that it would have been collected during the clinical trial and thus would be important to the interpretation of results.

We specify this requirement in proposed § 11.48(a)(2)(iii) which requires, in addition to age and gender, the submission of information for each baseline or demographic characteristic measured in the clinical trial that is used in the analysis of any of the

outcome measures (See section IV.C.4.c of this preamble for a discussion of outcome measures). In order for submitted demographic and baseline characteristic information to be meaningful to users, we specify that the responsible party must submit the following information for each demographic or baseline measure submitted to ClinicalTrials.gov: the Name of the measure (e.g., gender) and Description of the measure (e.g., ''male'' and ''female''); the type of measure (Measure Type) and an associated Measure of Dispersion; and the unit of measure (e.g., milligrams). When specifying the Measure Type, the responsible party would have to select from the following limited list of options: ''number,'' ''mean,'' ''median,'' ''least squares mean,'' ''geometric mean,'' or ''log mean.'' When specifying the associated Measure of Dispersion, the responsible party would have to select from the following limited list of options: ''standard deviation,'' ''inter-quartile range,'' ''full range,'' or ''not applicable'' (which would be permitted only if the specified measure type is ''number''). No ''other'' option is proposed for either the Measure Type or Measure of Dispersion, but responsible parties would have the option of providing voluntarily additional information about the baseline measures as part of a free-text Baseline Measure Description. We believe that this approach would allow a responsible party to accurately describe the baseline characteristics of an applicable clinical trial or other clinical trial that is subject to this proposed rule. We invite public comment on the sufficiency of the proposed approach for submitting baseline characteristics.

Collecting the information in the structured manner proposed is intended to improve the comparability of information across clinical trials and to ensure complete data collection. For example, if a responsible party indicates that the measure of dispersion for a measure is interquartile range, for example, ClinicalTrials.gov could prompt the submission of the two data elements needed to specify the upper and lower bounds of the interquartile range; if a responsible party indicates that the measure of dispersion is a standard deviation, ClinicalTrials.gov could prompt the submission of that single value. Note that baseline characteristic information may also be submitted as a number instead of a central tendency (e.g. number of participants), in which case the measure of dispersion must be indicated as ''Not Applicable.''

We invite comments on whether or not we should require the submission of additional demographic or baseline characteristics that were collected during the clinical trial, the advantages and disadvantages of requiring the submission of such information, and, if so, how such information can be specified in the rule. We also invite comments on other types of demographic information that could be required for all clinical trials, for example, country-of-origin or country-of-residence, which are collected in many clinical trials. We invite comment on whether the fixed list of proposed choices for measures of central tendency and of dispersion is adequate to provide an accurate description of the measures used in any clinical trial.

Our proposal for demographic and baseline characteristics indicates that responsible parties should submit such information by ''arm or comparison group.'' The reference to comparison group recognizes that when analyzing data collected during clinical trials, data are often aggregated into groupings of human subjects (i.e., comparison groups) other than the arms into which they were assigned for the study. This is often the case in clinical trials that use a cross-over study design in which human subjects in different arms of the clinical trial receive the same interventions in a different order; the results are often analyzed not by arm but by intervention (See the discussion of comparison group in section IV.A.5). We believe it is appropriate when submitting demographic and baseline characteristics, as well as other results information, that the information to be submitted according to the same groupings by which it was analyzed, whether the arm of the clinical trial or a different comparison group. So that users of ClinicalTrials.gov can understand how information about human subjects was aggregated for analysis, proposed § 11.48(a)(2)(i) requires submission of a Baseline Characteristic Arm/Group Information data element, which consists of ''[a] brief description of each arm or comparison group used for describing the demographic and baseline characteristics of the human subjects in the clinical trial, including a descriptive title used to identify each arm or comparison group.''

We also propose in § 11.48(a)(2)(ii) to require submission of Overall Number of Baseline Participants, ''[t]he total number of human subjects for whom baseline characteristics were measured, by arm or comparison group and overall.'' This information is necessary to indicate whether some subjects enrolled in the clinical trial were not measured at baseline (e.g., because they dropped out of the clinical trial before that point in time) and to help ensure that results information is submitted for all subjects who were measured at baseline.

(c) Outcomes and statistical analyses: Section 402(j)(3)(C)(ii) of the PHS Act requires the following as results information: ''The primary and secondary outcome measures as submitted under paragraph (2)(A)(ii)(I)(ll), and a table of values for each of the primary and secondary outcome measures for each arm of the clinical trial, including the results of scientifically appropriate tests of the statistical significance of such outcome measures.'' As discussed in section IV.B.4 of this preamble, primary and secondary outcome measures are submitted as part of the registration process. ClinicalTrials.gov was designed to display the results of each pre-specified outcome measure (primary or secondary) in separate tables organized by arm or comparison group. The responsible party determines the rows and columns of each outcome measure table: The columns represent arms or comparison groups, and the rows represent data categories (e.g., for categorical data types) and data attributes (e.g., mean and standard deviation). The responsible party populates the table cells with data from the clinical trial. In this way, the system can accommodate either continuous or categorical data, as desired by the responsible party based upon the design of the clinical trial as specified in the protocol and statistical analysis plan. For example, time-to-event data could be provided as either a continuous measure (e.g., median time to response) or as categorical data (e.g., number of participants with response at five-years).

In order to enhance the ability of users to understand and interpret the submitted clinical trial results information and to help ensure that submitted information is complete, we propose in §§ 11.48(a)(3)(i)–(v) that the responsible party submit the following information to create and populate the outcome data tables:

(1) Outcome Measure Arm/Group Information, which is described as ''[a] brief description of each arm or comparison group used for submitting an outcome measure for the clinical trial, including a descriptive title to identify each arm or comparison group.'' As discussed in the section IV.C.4(b) on demographic and baseline characteristics, this information would describe the grouping of human subjects for purposes of analysis, whether by arm

of the clinical trial or other comparison group.

(2) Analysis Population Information, which must include the Number of Participants Analyzed, meaning ''[t]he number of human subjects for which an outcome was measured and analyzed, by arm or comparison group.'' If the analysis is based on a unit other than human subjects (e.g., lesions, eyes, implants), the responsible party would also be required to provide the Number of Units Analyzed, which is defined as ''. . . a description of the unit of analysis and the number of units for which an outcome was measured and analyzed, by arm or comparison group.'' In addition, if the Number of Participants Analyzed in an arm or comparison group differs from the number of human subjects assigned to the arm or comparison group, the responsible party would also be required to provide an Analysis Population Description, which would briefly describe the reason(s) for the difference (e.g., if a clinical trial is terminated after participants are assigned to arms but before one of the outcome measures is assessed, the responsible party would include a statement in the Analysis Population Description indicating that the clinical trial was terminated before the outcome measure was collected). This entry would explain why the total Number of Participants Analyzed is zero even though participants had been assigned to the relevant arm or comparison group.

(3) Outcome Measure Information, which includes the following components: (A) Name of the specific outcome measure, including the titles of any categories into which outcome measure data are aggregated; (B) Description of the metric used to characterize the specific outcome measure; (C) Time point(s) at which the measurement was assessed for the specific metric; (D) Outcome Measure Type, which indicates whether the outcome measure is one of the following types of outcome measure: Primary outcome measure, secondary outcome measure, other pre-specified outcome measure, or post-hoc outcome measure; (E) Outcome Measure Reporting Status, which indicates whether the data for the outcome measure are included in the present submission and, if not, the anticipated submission date; (F) Measure Type, which indicates whether the outcome is measured as a number (e.g., number of subjects with a measured value of hemoglobin 5% above the baseline value) or a measure of central tendency, and the associated Measure of Dispersion or precision; and (G) Unit of Measure (e.g., blood pressure in ''millimeters of mercury'' or ''percent change''). In specifying a Measure Type, the responsible party would be required to select from the following limited list options: ''number,'' ''mean,'' ''median,'' ''least squares mean,'' ''geometric mean,'' or ''log mean.'' In specifying the associated Measure of Dispersion, the responsible party would be required to select from the following limited set of options: ''standard deviation,'' ''inter-quartile range,'' ''full range,'' ''standard error,'' ''95% confidence interval,'' ''90% confidence interval,'' ''geometric coefficient of variation'' (which would be permitted only if the specified Measure Type is ''geometric mean''), or ''not applicable'' (which would be permitted only if the specified Measure Type is ''number''). No ''other'' option is proposed for either the Measure Type or Measure of Dispersion entries, but responsible parties would have the option of voluntarily providing additional descriptive information about the outcome measure type and measure of dispersion as part of a free-text Outcome Measure Description. We propose to collect Measure Type and Measure of Dispersion in this manner to improve the ability to compare submitted information across clinical trials and to ensure complete data submission, e.g., if the responsible party indicates that the Measure of Dispersion is interquartile range, ClinicalTrials.gov can prompt the submission of two values corresponding to the upper and lower bounds of the interquartile range, instead of just the single value needed to submit a standard deviation. We invite public comment on this proposal and whether the proposed options for Measure Type and Measure of Dispersion are sufficient for collecting data from the full range of applicable clinical trials or voluntarily submitted trials that would be subject to this proposed rule.

In most cases, items (A), (B), and (C) above would have been submitted at the time of clinical trial registration and updated during the course of the clinical trial, as specified in proposed § 11.64. Proposed § 11.64(c) specifically requires that responsible parties update information submitted during registration at the time they submit results. To ensure consistent data entry and reduce the data entry burden on responsible parties, ClinicalTrials.gov would automatically pre-populate the results data tables with the previously submitted (and updated) values and allow the responsible party to make further updates, as necessary or desired (e.g., to provide further clarification that would enable a user to better interpret the submitted results values). If data were not collected for an outcome measure in a clinical trial, i.e., the Number of Participants Analyzed in all arms or comparison groups is zero for that outcome measure, the responsible party would not be required to submit items (F) and (G) for that outcome measure, as no Outcome Measure Data would be submitted. This situation might occur, for example, if a clinical trial is terminated before data are collected for all pre-specified outcome measures.

(4) Outcome Measure Data, which consists of the measurement values for each outcome measure for which data were collected, by arm or comparison group. The information provided under Outcome Measure Data must use the Unit of Measure and correspond to the Outcome Measure Type submitted under (3) above, i.e., be a number or a central tendency plus a measure of dispersion or precision.

(5) Statistical analyses, which are specified in proposed § 11.48(a)(v) as the ''[r]esults of scientifically appropriate statistical analyses, if any . . .'' performed on the primary or secondary outcome measure(s). In implementing this requirement we clarify the meaning of ''scientifically appropriate'' as it relates to statistical analyses. We believe that the scientific appropriateness of a statistical analysis in a clinical trial is inherently subjective. For purposes of this rule, we propose that a statistical analysis that meets any of the following criteria be considered scientifically appropriate in the context of a particular applicable clinical trial: (1) The statistical analysis is pre-specified in the protocol or statistical analysis plan; (2) the statistical analysis is made public by the sponsor or responsible party in written form (e.g., in a journal publication) prior to the date on which results submission is otherwise completed for all primary and secondary outcome measures studied in the clinical trial; or (3) the statistical analysis is conducted in response to a specific request from the FDA that is made before complete results information is submitted for all of the primary outcome measures studied in the clinical trial. We limit the requirement to submit FDA-requested statistical analyses to those analyses that are requested prior to the submission of results information for primary outcome measures only, so as to avoid causing a responsible party to have to submit analyses that are requested on data that were previously submitted to ClinicalTrials.gov. We propose that statistical analyses that meet any of

these criteria be submitted to ClinicalTrials.gov at the time of results submission. We clarify that a responsible party would not be required to submit a statistical analysis that is not pre-specified in the protocol or statistical analysis plan, is published after complete results information is submitted to ClinicalTrials.gov, or is requested by the FDA after the date on which complete results information is submitted for all of the primary outcome measures studied in the clinical trial. We further clarify that the requirement to submit results of any scientifically appropriate statistical analyses would not cause a responsible party to conduct a statistical analysis that was not otherwise planned or required. We invite public comments on these proposals and on other criteria the agency should consider determining what constitutes a ''scientifically appropriate'' statistical analysis.

We specify in proposed § 11.48(a)(3)(v) the information that a responsible party must submit for any scientifically appropriate analysis:

(A) Statistical Analysis Overview: The responsible party would identify the arms or comparison groups compared in the statistical analysis (by selecting the arms or comparison groups already defined for the outcome measures) and specify the type of analysis conducted. The type of analysis conducted would be selected from the following limited set of options: ''superiority,'' ''non-inferiority,'' ''equivalence,'' or ''not applicable,'' where ''not applicable'' would be appropriate for a single group analysis, for example. No ''other'' option is proposed. If the type of analysis selected is ''non-inferiority'' or ''equivalence,'' the responsible party would be required to also provide a free-text description of key parameters of the statistical analysis to include, at minimum, information about the power calculation and the non-inferiority or equivalence margin. An additional comment field would be offered to allow the responsible party to voluntarily submit additional information about the statistical analysis. We invite comment on whether the list of proposed options is sufficient for all applicable clinical trials or voluntarily submitted clinical trials for which statistical analysis information might be submitted to ClinicalTrials.gov under this proposed rule.

(B) Statistical Test of Hypothesis: The responsible party would submit the p-value and specify the procedure used for statistical analysis of the outcome data. For convenience in specifying the procedure used for the statistical analysis, ClinicalTrials.gov includes a list of commonly used statistical tests for calculating p-values from which responsible parties may select: ANCOVA; ANOVA; Chi-squared; Chi-squared, Corrected; Cochran-Mantel-Haenszel; Fisher Exact; Kruskal-Wallis; Log Rank; Mantel Haenszel; McNemar; Mixed Models Analysis; Regression, Cox; Regression, Linear; Regression, Logistic; Sign Test; t-Test, 1-sided; t-Test, 2-sided; and Wilcoxon (Mann-Whitney). Responsible parties may also select ''other'' and submit the name of another method that was used. Additional comment fields would be available in ClinicalTrials.gov to allow the responsible party to submit voluntarily additional information about the statistical test of hypothesis, such as a description of the null hypothesis, adjustments for multiple comparisons, a priori thresholds for statistical significance, and degrees of freedom.

(C) Method of Estimation: The responsible party would provide a description of the method of estimation that specifies: The estimation parameter, the estimated value, and a confidence interval. For convenience in describing the method of estimation, ClinicalTrials.gov includes a list of more than a dozen commonly used estimation parameters from which responsible parties may select: Cox Proportional Hazard; Hazard Ratio (HR); Hazard Ratio, log; Mean Difference (Final Values); Mean Difference (Net); Median Difference (Final Values); Median Difference (Net); Odds Ratio (OR); Odds Ratio, log; Risk Difference (RD); Risk Ratio (RR); Risk Ratio, log; and Slope. Responsible parties may also specify ''other'' and provide the name of another estimation parameter using free text. In specifying a confidence interval, the responsible party would submit the confidence level, indicate whether the confidence interval is one-sided or two-sided, and provide the upper and/or lower limits of the confidence interval. A responsible party could specify that the confidence interval is one-sided and provide only the upper or lower limit. If one of the limits of a two-sided confidence interval cannot be calculated, the responsible party would be required to specify that limit as ''Not Available'' and provide a brief narrative explanation (e.g., because an insufficient number of clinical trial participants reached the event at the final time point for assessment). A responsible party would also have the option of submitting voluntarily a dispersion value for the confidence interval. If a dispersion value is submitted, the responsible party would be required to specify the parameter of dispersion by selecting one of the following options: ''Standard deviation'' or ''standard error of the mean.'' No ''other'' option is proposed. An additional comment field would be available to allow the responsible party to submit voluntarily additional information about the method of estimation, such as the direction of the comparison (e.g., for a relative risk).

These proposed requirements for submitting statistical analysis information attempt to balance the benefits of structured data with minimal narrative text against the need to describe what was evaluated in the statistical analysis. In addition to the information specified above, responsible parties also would have the option of voluntarily submitting additional free-text information in order to provide a more complete description of the statistical analyses. This free-text information would not include interpretation of results or conclusions, just a description of the statistical test(s) conducted. Submitted statistical analyses would be linked to each submitted outcome measure. Although a responsible party would not be limited in the number of statistical analyses that could be submitted for each outcome measure, only statistical analyses that are related to a submitted outcome measure could be described.

In specifying requirements for outcome measures and statistical analyses under proposed § 11.48(a)(3), two situations merit further clarification. The first is a clinical trial that is terminated before data are collected for one or more of the pre-specified outcome measures. Certain information would still be required to be submitted for outcome measures for which data were not collected. Under proposed § 11.48(a)(3)(ii) the responsible party would be required to submit the Number of Participants Analyzed, which would be zero (''0'') for an outcome measure for which no data were collected. As noted in (3) above and specified in proposed § 11.48(a)(3)(iii)(F) and (G), the responsible party would not be required to submit the Measure Type and Unit of Measure data elements for any outcome measure for which data were not collected but would be required to provide the other elements of Outcome Measure Information specified in proposed § 11.48(a)(3)(iii). As specified in proposed § 11.48(a)(3)(iv), the responsible party would not be required to submit Outcome Measure Data for the outcome measure(s) for which no data were collected, but would be required to submit Outcome Measure Data for any

other outcomes for which data were collected. The responsible party would nevertheless still be required to meet the requirements specified in proposed §§ 11.48(a)(1), (2), and (4) for the submission of information for the Participant Flow, Baseline Characteristics, and Adverse Events modules. Note, that if a clinical trial enrolls no participants, the information to be submitted for the Actual Enrollment data elements under proposed § 11.64(b)(1)(v)(B) would be zero (''0'') and no results information would be required to be submitted for that clinical trial.

The second situation consists of a clinical trial in which outcome measures are collected but the actual enrollment falls well below the target enrollment. This could occur, for example, if a clinical trial is terminated due to poor enrollment after some participants are enrolled and outcomes are measured. We believe that even in such situations collected results information must be submitted to ClinicalTrials.gov as specified in this proposed rule (taking into consideration the privacy considerations discussed in section III.C.16 of this preamble if actual enrollment is very small). Submission and posting of results information for such a clinical trial would be consistent with section 402(j) of the PHS Act and provide a means of tracking the progress of the clinical trial and demonstrating what happened to the human subjects who were enrolled. If the clinical trial was terminated because of safety concerns or efficacy, the results information would be of considerable interest to human health and safety. In order to reduce the chance that users of ClinicalTrials.gov might misinterpret submitted results information, we would encourage the responsible party to voluntarily submit additional information about the clinical trial in the Analysis Population Description data element and/or in the Limitations and Caveats module of ClinicalTrials.gov. The submitted information would highlight that enrollment in the clinical trial was insufficient to produce statistically reliable results. We would also take steps to highlight in the public display the fact that actual enrollment fell far short of expected enrollment. We would expect that in these situations, no statistical analysis information would be submitted for the affected outcome measure(s) because none would have been conducted or would be considered scientifically valid. We invite public comments on other ways in which the limitations of the submitted data could be highlighted.

(d) Adverse event information. Proposed § 11.48(a)(4) requires the submission of summary information on adverse events that occurred during an applicable clinical trial. Such information is considered part of results information. Our proposal derives from the default provisions in sections 402(j)(3)(I)(ii)–(iii) of the PHS Act, which require the submission of information necessary to complete two tables: (1) A table of all anticipated and unanticipated serious adverse events, and (2) a table of all anticipated and unanticipated adverse events other than serious adverse events with a frequency of more than 5 percent in any arm of the clinical trial (i.e., ''other frequent adverse events''). Sections 402(j)(3)(I)(ii)–(iii) of the PHS Act further specify that the information submitted for each table be grouped by organ system and include the number and frequency of events in each arm of the clinical trial. As explained in greater detail in section III.C.15 of this preamble, our proposal for the submission of adverse event information derives from the default provisions in sections 402(j)(3)(I)(ii)–(iii) of the PHS Act, but includes additional requirements intended to assist users in understanding and interpreting the submitted adverse event information.

In implementing the statutory default provisions, we propose in § 11.48(a)(4) that responsible parties submit the following information for all serious adverse events and for other adverse events with a frequency of more than 5 percent in any arm or comparison group of the clinical trial: (1) A description of each arm or comparison group from which adverse event information was collected (see proposed § 11.48(a)(4)(ii)(A)); (2) for each arm or comparison group, a description of each serious adverse event or other adverse event with a frequency of more than 5 percent in any arm of the clinical trial, along with the organ system that is associated with the adverse event (see proposed § 11.48(a)(4)(ii)(F)); (3) the number of participants experiencing the adverse event (see proposed § 11.48(a)(4)(ii)(G)(1)), and (4) the number of participants at risk for the adverse event (see proposed § 11.48(a)(4)(ii)(G)(2)). In most cases, the number of participants at risk will equal the number of participants who started that arm of the clinical trial, but the two numbers could differ if participants were assigned to an arm but did not receive the intervention (e.g., because they dropped out of the clinical trial) or because a comparison group combines participants from multiple arms of the trial. Using the data submitted for number of participants experiencing the adverse event and the number of participants at risk, ClinicalTrials.gov will automatically calculate the percentage of participants who experienced the event. We believe that this approach will help reduce calculation errors and help users interpret the frequency information in those cases in which the full study population may not have been at-risk.

To assist users of ClinicalTrials.gov in better understanding the number of participants affected by adverse events, we also propose in § 11.48(a)(4) that responsible parties be required to submit the following information both for all serious adverse events and for other adverse events with a frequency of more than 5 percent in any arm or comparison group of the clinical trial: (1) The overall number of human subjects affected, by arm or comparison group, by one or more serious adverse events or other adverse events above the specified threshold (see proposed § 11.48(a)(4)(ii)(B)), (2) the overall number of participants at risk for any adverse event, by arm or comparison group (see proposed § 11.48(a)(4)(ii)(C)), (3) for each organ system class that has one or more adverse events listed in either table, the overall number of participants affected, by arm or comparison group, by any adverse event in that organ system class (see proposed § 11.48(a)(4)(ii)(D)), and (4) for each organ system class that has one or more adverse events listed in either table, the number of participants at risk, by arm or comparison group, for any adverse event in that organ system class (see proposed § 11.48(a)(4)(ii)(E)). ClinicalTrials.gov will automatically calculate the percentage of those at risk that experienced any adverse event and the percentage of those at risk that experienced any adverse event in each organ system class. We believe that this approach will help reduce calculation errors and help users interpret the frequency information in those cases in which the full study population may not have been at-risk for any adverse event or for adverse events affecting particular organ systems.

As explained in section III.C.5 of this preamble, we propose to require responsible parties to submit adverse event information classified according to the scheme specified in ClinicalTrials.gov, which includes the following 26 categories adapted from the Medical Dictionary for Regulatory Affairs (MedDRA) system (*http://www.meddramsso.com/*): Blood and lymphatic system disorders; Cardiac

disorders; Congenital, familial and genetic disorders; Ear and labyrinth disorders; Endocrine disorders; Eye disorders; Gastrointestinal disorders; General disorders; Hepatobiliary disorders; Immune system disorders; Infections and infestations; Injury, poisoning and procedural complications; Investigations; Metabolism and nutrition disorders; Musculoskeletal and connective tissue disorders; Neoplasms benign, malignant and unspecified (including cysts and polyps); Nervous system disorders; Pregnancy, puerperium and perinatal conditions; Psychiatric disorders; Renal and urinary disorders; Reproductive system and breast disorders; Respiratory, thoracic and mediastinal disorders; Skin and subcutaneous tissue disorders; Social circumstances; Surgical and medical procedures; and Vascular disorders organ classes. No ''other'' option is proposed. ''Social circumstances'' is a not an organ class (like most of the other categories) but is used in MedDRA to accommodate the classification of some types of adverse events that are not specific to an organ system, such as ''automobile accident,'' ''homicide,'' or ''fall''. Adverse events that affect multiple systems should be reported only once (to avoid over-counting), preferably under the organ system class that is considered primary. If there is no primary organ system class, the event should be listed under ''General disorders,'' and additional explanation may be provided in the optional free-text field, Adverse Event Term Additional Description. Our experience with submission of adverse event information since September 2008 indicates that responsible parties are able to use these classes effectively to classify the adverse event information submitted to ClinicalTrials.gov. We request comment on whether this organ system classification is sufficient for submitting adverse event information for all applicable clinical trials and voluntarily registered trials that are subject to this rule, or whether additional categories or an ''other'' option are necessary.

As specified in the statutory default provisions, the adverse event information submitted under proposed § 11.48(a)(4)(ii)(G)(1) and (2) would be required to include information on anticipated and unanticipated adverse events. We understand that protocols sometimes specify the collection of only a more limited set of adverse events in a clinical trial, e.g. only unanticipated events, or only events associated with a particular organ system. We do not intend this proposed rule to cause investigators or responsible parties to collect information that is not specified in the clinical trial protocol. Therefore, in those situations in which the protocol specifies a more limited collection of adverse events, we would require the responsible party to submit the specified information about serious and other adverse events with a frequency greater than 5 percent in any arm of the trial for those adverse events that were collected during the trial. To help ensure that users of ClinicalTrials.gov know when adverse event collection was limited, the responsible party would be further required, as indicated in proposed § 11.48(a)(4)(ii)(H), to submit an Additional Description that briefly describes how the scope of adverse events for which information was submitted differs from the broader definitions of adverse event and serious adverse event proposed in this rule.

Finally, we note that the agency interprets section 402(j)(3)(I)(v) of the PHS Act to deem the adverse event information required under section 402(j)(3)(I) of the PHS Act as clinical trial information for all clinical trials, including applicable clinical trials and voluntarily-submitted clinical trials.

(e) Administrative information: Proposed § 11.48(a)(5) describes certain administrative information that we propose to require to be submitted as results information data elements. Section 402(j)(3)(C)(iii) of the PHS Act requires that ''a point of contact for scientific information about the clinical trial results'' be submitted as part of clinical trial results information. Proposed § 11.48(a)(5)(i) implements this provision by requiring the following information: (1) Name or official title of the point of contact; (2) name of affiliated organization; and (3) telephone number and email address of the point of contact. We believe that this is the information is needed in order to allow a user to inquire about the results of the clinical trial. This information would be required to be submitted, even if the point of contact is the same as the responsible party because we do not otherwise plan to make public the responsible party contact information.

Section 402(j)(3)(C)(iv) of the PHS Act requires responsible parties to indicate ''whether there exists an agreement . . . between the sponsor or its agent and the principal investigator . . . that restricts in any manner the ability of the principal investigator, after the completion date of the trial, to discuss the results of the trial at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the trial.'' The statutory provision also provides that this requirement does not apply to an agreement between a sponsor or its agent and the principal investigator solely to comply with applicable provisions of law protecting the privacy of participants in the clinical trial. Consistent with the definition of PI proposed in this part, we interpret this provision as applying to a PI who has oversight over the entire applicable clinical trial, not to site-specific investigators or other investigators (such as those on grant-funded studies) who might be referred to as principal investigators in other contexts but who do not meet the definition of ''principal investigator'' under this part.

In implementing the requirement under section 402(j)(3)(C)(iv) of the PHS Act, we propose in § 11.48(a)(5)(ii) to require responsible parties to indicate (yes/no) whether the PI is an employee of the sponsor. If the PI is an employee of the sponsor, then no further information must be provided, although it may be provided voluntarily. If the responsible party indicates that the PI is not an employee of the sponsor, then the responsible party would be required to indicate (yes/no) whether or not an agreement (other than one solely to comply with applicable provisions of law protecting the privacy of human subjects participating in the clinical trial) exists between the sponsor or its agent and the PI that restricts in any manner the ability of the PI, after the completion date of the clinical trial, to discuss the results of the clinical trial at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the clinical trial.

Although we are only requiring, consistent with section 402(j)(3)(C)(iv) of the PHS Act, that the responsible party indicate whether such an agreement exists, we also propose to permit responsible parties to provide voluntary additional information about existing agreements. In our interactions with responsible parties and consultations with stakeholders, we have learned that certain agreements of the nature described in section 402(j)(3)(C)(iv) of the PHS Act exist routinely in the clinical trials community, although they may vary in their terms and the duration of their limitations on the PI. Such agreements typically permit the sponsor or its agent to review results communications prior to public release and to impose a short-term embargo of 60 days or less, from the date the communication is submitted to the sponsor for review, but other agreements can impose

restrictions that have much longer durations or are broader in scope. In order to provide responsible parties with an opportunity to provide additional information about the agreements that are in place between the sponsor or its agent and the PI, we propose to permit the voluntary submission of additional, structured information about the agreement. Currently in ClinicalTrials.gov, a responsible party who wishes to provide this additional information may select among the following choices:

(1) The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding clinical trial results for a period that is less than or equal to 60 days from the date the communication is submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

(2) The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding clinical trial results for a period that is more than 60 days but less than or equal to 180 days from the date the communication is submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.

(3) Other disclosure agreement that restricts the right of the PI to discuss or publish clinical trial results after the trial is completed. The responsible party may provide additional description of the disclosure agreement.

Based on our experience to-date in operating ClinicalTrials.gov and on feedback we have received from responsible parties, these categories appear to provide an acceptable way to describe these agreements in a consistent form and manner that can help identify those that deviate from standard practice. These categories could be modified over time in order to reflect changes in clinical trials practice or provide other information of interest to users. We invite public comment on the proposed approach, experience to date with the current approach, and other information that might be collected on a voluntary basis.

(f) Additional results information for applicable device clinical trials of unapproved or uncleared devices. For applicable device clinical trials of unapproved or uncleared devices, the results information specified in (a) through (e) above would be submitted to ClinicalTrials.gov and publicly posted prior to the date on which clinical trial information submitted at the time of registration would have been publicly posted. As a result, users of ClinicalTrials.gov would lack access to certain descriptive information that is necessary to enhance access to and understanding of the submitted results information and to determine whether complete results information has been submitted (e.g., for all arms of the study).

Section 402(j)(3)(D)(iii)(IV) of the PHS Act grants the Secretary wide discretion in determining what information can be required through rulemaking to be submitted as part of results information, stating that the regulations ''shall require, in addition to the elements described in [section 402(j)(3)(C)] . . . [s]uch other categories as the Secretary determines appropriate.'' Thus, the Secretary can require, through rulemaking, submission of not only that results information that is required under section 402(j)(3)(C) of the PHS Act, but also ''such other categories'' of information as the Secretary determines appropriate. We interpret ''such other categories'' of results information for applicable device clinical trials of unapproved or uncleared devices to include, among other things, certain descriptive information that is the same type of information that was required to be submitted under section 402(j)(2)(A)(ii) of the PHS Act.

In order ''to enhance patient access to and understanding of the results of clinical trials'' (See section 402(j)(3)(D)(i) of the PHS Act), we propose to exercise the authority under sections 402(j)(3)(D)(ii)(II) and 402(j)(3)(D)(iii) of the PHS Act to require responsible parties of applicable device clinical trials of unapproved or uncleared devices to submit, as part of results information, certain additional, descriptive information that is the same type of information that is submitted at the time of registration. This descriptive information, defined as part of results information, would be posted not later than 30 calendar days after submission, pursuant to section 402(j)(3)(G) of the PHS Act. A more detailed discussion of how the specified data elements would enhance access to and understanding of clinical trial results information is contained in section III.C.5 of this preamble.

Proposed § 11.48(a)(6)(i) lists the descriptive information we propose that responsible parties must submit as part of the clinical trial results information submitted for applicable device clinical trials of unapproved or uncleared devices. We believe that the listed data elements are necessary to enhance access to and understanding of the results of applicable clinical trials of unapproved or uncleared devices for which information submitted at registration would not have been posted publicly in ClinicalTrials.gov. We interpret this necessary standard broadly to enhance access to and understanding of study results by the lay public, as well as users of the data bank who have high levels of expertise in evaluating the results of clinical trials. Moreover, we interpret this necessary standard broadly to enhance access to and the understanding of results of clinical trials that are posted in ClinicalTrials.gov as well as those that are not posted in ClinicalTrials.gov; for example: the comparison of the results of multiple clinical trials of the same or similar devices may be necessary to understand the results of a clinical trial. We further believe that information indicating the status of any necessary human subjects protection review board approval must be submitted so that users can understand whether results information voluntarily submitted to ClinicalTrials.gov and available in the data bank derives from clinical trials that were reviewed and approved for ethical and scientific considerations, or were exempt from such review.

Because responsible parties for applicable device clinical trials of unapproved or uncleared devices will already have provided this descriptive information to the data bank when submitting (and updating, as necessary) registration information, the agency believes that it would be an unnecessary burden on these responsible parties to require them to resubmit descriptive information as part of clinical trial results information. Instead, we propose under § 11.48(a)(6)(ii) to require responsible parties to affirm that they have verified and updated as necessary the descriptive information that is the same type of information that is submitted when the trial is registered and that this descriptive information is ready to be posted along with the results information. Doing so would allow information that previously had been submitted to the data bank to automatically populate the data elements for these clinical trial results. This approach would also reduce inconsistencies between information that previously had been submitted at registration and information that would be submitted with results, and increase administrative efficiency by reducing the need for the agency to conduct a quality review of this information. In this manner, we can help ensure that the results information necessary ''to

enhance patient access to and understanding of the results of clinical trials,'' section 402(j)(3)(D)(i) of the PHS Act, is submitted and made available publicly, but can reduce the burden placed on responsible parties.

(g) Results information for a pediatric postmarket surveillance of a device that is not a clinical trial. Subsection (b) of proposed § 11.48 specifies the results information that must be submitted to ClinicalTrials.gov for a pediatric postmarket surveillance of a device that is not a clinical trial. We recognize that a pediatric postmarket surveillance of a device may take any of several forms, including prospective surveillance studies and historical reviews of the health records of those who have received a device as an intervention, and may not meet the definition of a ''clinical trial'' under this part. For this reason, we do not believe that it is possible to specify particular data elements or tables of data, similar to those for applicable clinical trials that are clinical trials, that could be required as results information for all types of pediatric postmarket surveillances of a device that are not clinical trials. We are aware, however, that for each pediatric postmarket surveillance of a device that is required by FDA, a final report must be submitted to FDA according to 21 CFR 822.38 (or any successor regulation). Thus, for each pediatric postmarket surveillance of a device that is not a clinical trial, we believe that the final report would contain a suitable summary of the surveillance results, and we propose that it be submitted to ClinicalTrials.gov in a form that can be made available to the public, e.g., after redacting: (a) Any personally identifiable information (other than that required to be submitted under this part), and (b) information that is not required to be submitted under this part and that is commercial confidential information. Any information not redacted would be included in the public data bank. The final report would be required to be submitted in a common electronic document format, such as Portable Document Format (PDF) or Microsoft Word, specified in ClinicalTrials.gov at *http://prsinfo.clinicaltrials.gov/*. The set of acceptable formats may be updated periodically to include new formats that become commonly used in the regulated community. This proposed requirement is included in section 11.48(b). We invite public comment on this approach.

5. When will NIH post submitted results information?—§ 11.52

Proposed § 11.52 provides that the Director will post results information not later than 30 days after the date on which the information is submitted to the agency for an applicable clinical trial. This proposal corresponds to the posting deadline established in section 402(j)(3)(G) of the PHS Act. Proposed § 11.52 does not apply to clinical trials that are not required to register under 402(j)(2)(C) of the PHS Act. For such trials that voluntarily register with ClinicalTrials.gov, regardless of whether they are subject to the requirements for voluntary submission under proposed § 11.60 or are subject to the requirements in § 11.60(a)(2)(ii), we intend to post results information as soon as practicable after clinical trial results information has been submitted and reviewed as part of our quality review procedures.

6. Under what circumstances will the Secretary grant a waiver of the requirements of this subpart?—§ 11.54

Section 402(j)(3)(H) of the PHS Act provides that ''[t]he Secretary may waive any applicable requirements of this paragraph for an applicable clinical trial, upon written request from the responsible party, if the Secretary determines that extraordinary circumstances justify the waiver and that providing the waiver is consistent with the protection of public health or in the interest of national security . . .'' Proposed § 11.54, implements this provision by outlining procedures by which a responsible party may submit a written request for a waiver from the requirements of subpart C for an applicable clinical trial in extraordinary circumstances where provision of the waiver is consistent with protecting public health or in the interest of national security.

We expect that waivers would be requested and granted in only a very limited number of situations. As described in section III.C.16 of this preamble, one example of a situation in which a waiver might be granted is if results information could be submitted only in a manner that would be likely to enable the re-identification of clinical trial participants. We invite public comments on other situations in which a waiver might be granted and would be consistent with the protection of public health or in the interest of national security.

The proposal specifies that waiver requests must be submitted in the form of a written letter to the Secretary or a delegated official and indicate the NCT Number, Brief Title, and Sponsor of the trial. This information is necessary to identify positively the specific trial for which the waiver is requested (the combination of NCT Number and Brief Title will assist in identifying mistyped NCT numbers) and the key parties involved (i.e., sponsor and responsible party). Because the statute grants the Secretary the authority to waive ''any applicable requirements'' of this subpart if justified by ''extraordinary circumstances'', we also propose that the responsible party identify the specific provisions(s) for which a waiver is requested and provide a description of the circumstances that are believed to justify the waiver.

The responsible party would not be required to comply with those provisions of subpart C for which the waiver was granted. Such provisions could include all or just some of the provisions for which the waiver was requested. The responsible party would be expected to comply with any remaining provisions of subpart C for which the waiver was not requested or not granted. The deadline for submitting results information to ClinicalTrials.gov would be the later of the original submission deadline or 15 calendar days after the notification denying the waiver is sent to the responsible party.

In subsection (b), we propose an appeals process that would permit a responsible party to appeal a denied waiver request by writing to the Secretary or delegated official. The delegated official for deciding upon waiver appeals would, as a matter of practice, differ from the delegated official for reviewing the initial waiver request. As with the original request, the responsible party would not be required to comply with specific provisions of subpart C for which the waiver is granted upon appeal; for those provisions for which a waiver is not granted upon appeal, the responsible party would be required to submit results information by the later of the original results submission deadline or 15 calendar days after the notification denying the appeal is sent to the responsible party.

As required by section 402(j)(3)(H) of the PHS Act, if such a waiver is granted, the Secretary will notify the appropriate Congressional committees that the waiver has been granted and explain why it has been granted, not later than 30 calendar days after any part of the waiver is granted. A notation would be made in the record for the applicable clinical trial in ClinicalTrials.gov to indicate that certain requirements for results submission have been waived, pursuant to section 402(j)(3)(H) of the

PHS Act. This notation is intended to inform users of ClinicalTrials.gov that the absence of certain results information does not constitute a failure to comply with the statute and implementing regulation. Because the waiver would be based on extraordinary circumstances that could include considerations of public health and/or national security, the agency proposes not to post publicly information describing the reason for the waiver. We invite public comment on this proposal.

D. Additional Submissions of Clinical Trial Information—Subpart D

Proposed subpart D describes requirements for additional submissions of clinical trial information to ClinicalTrials.gov, including: (1) Voluntary submission of clinical trial information for certain clinical trials that are not otherwise subject to the registration and results submission requirements of this proposed rule; (2) submission of clinical trial information when it is determined that posting of such information is necessary to protect public health; and (3) timelines for updating clinical trial information.

1. What requirements apply to the voluntary submission of clinical trial information for clinical trials of FDA-regulated drugs and devices?—§ 11.60

Proposed § 11.60 describes requirements that would apply to certain voluntary submissions of clinical trial information to ClinicalTrials.gov, specifically, submissions of information for clinical trials that are not otherwise subject to the registration and results submission requirements of section 402(j) of the PHS Act. This proposed section implements section 402(j)(4)(A) of the PHS Act which specifies certain requirements that apply to voluntary submissions of clinical trial information for two types of clinical trials for which submission of information is not otherwise required, as follows: (1) Clinical trials that do not meet the definition of an applicable clinical trial; and (2) clinical trials that are applicable clinical trials but are not required to register under section 402(j)(2)(C) of the PHS Act or proposed § 11.22(a) (i.e., clinical trials that are applicable clinical trials that were initiated on or before September 27, 2007, and that reached their completion dates before December 26, 2007).

If a responsible party wishes to submit clinical trial information voluntarily for one of these two types of clinical trials, the responsible party must: (1) Submit complete registration information as specified in proposed § 11.60(a)(2)(i)(A) or complete results information as specified in proposed § 11.60(a)(2)(i)(B) for the voluntarily-submitted clinical trial; and (2) submit clinical trial information for ''each applicable clinical trial that is required to be submitted under section 351 [of the PHS Act] or under section 505, 510(k), 515, or 520(m) of the [FD&C] Act in an application or report for licensure, approval, or clearance of the drug or device for the use studied in the clinical trial.'' (See section 402(j)(4)(A) of the PHS Act.) While the Agency encourages submissions of complete registration information and complete results information for all types of clinical trials, regardless of whether they are subject to section 402(j) of the PHS Act, responsible parties should consider the above conditions before deciding whether to register a clinical trial or submit results information voluntarily.

In considering which clinical trials fall under this provision, we believe that section 402(j)(4)(A) of the PHS Act should be interpreted in a way that is consistent with the scope of FDA's regulatory authorities and the scope of this proposed regulation. Hence, we interpret the phrase ''a clinical trial that is not an applicable clinical trial,'' in section 402(j)(4)(A) of the PHS Act, to be limited to a clinical trial of an FDA-regulated drug (including biological product) or device that is not an applicable clinical trial. We do not interpret this phrase to include clinical trials of other types of interventions, whether regulated by FDA or not, that would not meet the definition of an applicable clinical trial. Thus, proposed § 11.60 would apply, for example, to a phase 1 trial of an FDA-regulated drug, or to a clinical trial that evaluates the feasibility of an FDA-regulated device, but not to a clinical trial that studies only behavioral interventions that are not drugs, biological products, or devices. In addition, we interpret the phrase ''applicable clinical trial that is not subject to [the mandatory registration requirement of] paragraph (2)(C),'' in section 402(j)(4)(A) of the PHS Act, to mean a clinical trial that meets the definition of an applicable clinical trial, as specified in section 402(j)(1)(A) of the PHS Act and this part, but that was initiated on or before September 27, 2007, and that reached its completion date prior to December 26, 2007. This would mean that proposed § 11.60, and not proposed subparts B and/or C, would apply to submissions of clinical trial information for such applicable clinical trials.

In considering the information that must be submitted to ClinicalTrials.gov for a voluntarily-submitted clinical trial under section 402(j)(4)(A) of the PHS Act, we interpret section 402(j)(4)(A) of the PHS Act as permitting a responsible party to submit voluntarily registration information for a clinical trial without having to submit results information. Section 402(j)(4)(A) of the PHS Act uses the term ''or'' when referring to the submission of ''clinical trial registration information described in paragraph (2) [clinical trial registration information] or (3) [clinical trial results information]'' [emphasis added]. While we encourage those who register clinical trials voluntarily to also submit results information voluntarily, we see value in having voluntarily submitted registration information in ClinicalTrials.gov even if associated results information is not submitted. Clinical trial registration information can, for example, assist with recruitment and indicate the existence of a clinical trial. Similarly, we believe section 402(j)(4)(A) of the PHS Act permits a responsible party to submit voluntarily results information without having to have previously submitted registration information. Hence, proposed § 11.60(a)(2)(i) expressly permits the submission of registration information, results information, or both.

In specifying requirements for the voluntary submission of results information, proposed § 11.60(a)(2)(i)(B) requires the submission of the results information set forth at proposed § 11.48(a). However, we believe that certain descriptive information ordinarily submitted at the time of registration would be necessary to enhance access to results information, render it meaningful to the public, and demonstrate that the clinical trial is not an applicable clinical trial subject to proposed §§ 11.22 and 11.42. Thus, we propose that a responsible party who voluntarily submits only results information for a clinical trial under proposed § 11.60(a)(2)(i)(B), must submit the data elements set forth at proposed § 11.60(a)(2)(i)(B), in addition to the data elements set forth at proposed § 11.48(a), as clinical trial results information.

Sections III.C.5(b) and IV.C.4(f) of this preamble describe our rationale for requiring much of the descriptive information set forth at proposed § 11.60(a)(2)(i)(B). Those sections of the preamble, however, address only those data elements that we believe are necessary to enhance access to and understanding the results of a clinical trial of a device for which complete registration information has been previously submitted to ClinicalTrials.gov. We believe that

additional descriptive information is necessary to enhance access to and understanding of the results of a clinical trial of a drug (or a biological product): ''Study Phase'' is necessary to enable a user to understand the relative stage of development of an experimental drug (including biological product) studied in a clinical trial; and ''Availability of Expanded Access'' is necessary to provide patients with access to information about the availability of the drug to those who do not qualify for enrollment in the clinical trial.

In addition, we believe that several other data elements must be submitted with voluntarily submitted results information in order for users of the data bank and/or the Agency to confirm that a clinical trial for which information is submitted voluntarily is not an applicable clinical trial subject to mandatory registration or results submission under this part. Specifically, we believe that the following data elements are necessary: ''Single Arm Control?,'' ''Whether the Study is a Pediatric Postmarket Surveillance of a Device,'' ''Product Manufactured in the U.S.?,'' and ''U.S. Food and Drug Administration IND or IDE Number.''

For situations in which a responsible party submits voluntarily only clinical trial results information under section 402(j)(4)(A) of the PHS Act, we propose to use our authority under section 402(j)(3)(D)(iii)(IV) of the PHS Act to interpret results information to include the data elements under proposed § 11.60(a)(2)(i)(B) in addition to the data elements set forth at proposed § 11.48(a).

As stated, section 402(j)(4)(A) of the PHS Act specifies that voluntary submissions of information must consist of ''complete'' clinical trial registration or results information. We interpret the reference to ''complete'' in section 402(j)(4)(A) to mean that as a condition of voluntary submission under section 402(j)(4)(A) and proposed § 11.60, responsible parties must submit all registration information or results information data elements specified in proposed §§ 11.60(a)(2)(i)(A) or (B), as applicable. We note, however, that we propose in § 11.60(a)(2)(iv)(A) that a responsible party may submit results information for a voluntarily-submitted clinical trial once results information is available for the primary outcome measure(s). If data collection for the secondary outcome measure(s) for such clinical trials is not completed by the completion date of the voluntarily-submitted clinical trial, then results information for the secondary outcome measure(s) must be submitted by the later of the date that the results information is voluntarily submitted for the primary outcome measure(s) or 1 year after the date on which the final subject was examined or received an intervention for the purposes of final collection of data for the secondary outcome measure(s), whether the clinical trial was concluded according to the pre-specified protocol or was terminated.

Section 402(j)(4)(A) of the PHS Act also specifies that a responsible party who voluntarily registers or submits results information for a clinical trial must also submit clinical trial information for ''each applicable clinical trial that is required to be submitted under section 351 [of the PHS Act] or under section 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act in an application or report for licensure, approval, or clearance of the drug or device for the use studied in the clinical trial.'' We believe this condition of section 402(j)(4)(A) of the PHS Act may be intended to help prevent selective voluntary submissions, for example, if a responsible party voluntarily submitted clinical trial information only from clinical trials that showed positive results for a particular product, but not from clinical trials that showed negative or uncertain results for the same product. Voluntary submissions under section 402(j)(4)(A) of the PHS Act only trigger the required submission of clinical trial information for clinical trials that are applicable clinical trials (e.g., not phase 1 trials of a drug or small feasibility studies of a device) that were not required to be submitted to ClinicalTrials.gov under sections 402(i) or 402(j) of the PHS Act (e.g., those applicable clinical trials that were initiated on or before September 27, 2007, and reached their completion date prior to December 26, 2007).

One challenge in implementing this provision of section 402(j)(4)(A) of the PHS Act is that a responsible party who voluntarily submits clinical trial information about a clinical trial may not know at the time the voluntary submission is made which applicable clinical trials subsequently will be required to be included in a marketing application or premarket notification to FDA for the product for the use studied in the voluntarily-submitted clinical trial. Such a marketing application could be submitted many years after the completion date of the voluntarily-submitted clinical trial. Another challenge is that the responsible party for the voluntarily-submitted clinical trial might not be the responsible party for some or any of the applicable clinical trial(s) for which the submission of clinical trial information is triggered by the voluntary submission. As such, the responsible party voluntarily submitting clinical trial information for a clinical trial under section 402(j)(4)(A) of the PHS Act may not be aware of the triggered applicable clinical trial(s) and/or may not have access to the clinical trial information required to be submitted for such trials. In addition, a manufacturer who ultimately submits a marketing application or premarket notification may not be the responsible party for all of the applicable clinical trials that are required to be included in the marketing application or premarket notification, and might not have access to clinical trial information for those clinical trials.

To address these concerns, we propose in § 11.60(a)(2)(ii) to require a submission of clinical trial information for any triggered trials (i.e., for applicable clinical trials required to be included in a marketing application or premarket notification to FDA for approval, licensure, or clearance of the drug or device and that study the same use studied in the voluntarily-submitted clinical trial) only when the responsible party for the voluntarily-submitted clinical trial is also the manufacturer submitting the marketing application or premarket notification. This approach would reduce the likelihood of a responsible party making selective voluntarily submissions, consistent with our understanding of the intent of section 402(j)(4)(A) of the PHS Act, while ensuring that a responsible party would not be required to submit clinical trial information for a triggered applicable clinical trial for which he or she is not also the responsible party and does not have access to the relevant data. This approach also would avoid a situation in which one responsible party would be unaware that its clinical trials are subject to the requirements of section 402(j)(4)(A) of the PHS Act by virtue of a previous voluntary submission of clinical trial information made by another responsible party. We request public comment on our proposed approach in § 11.60(a)(2)(ii).

Section 402(j)(4)(A) of the PHS Act does not specify when information from each triggered applicable clinical trial must be submitted to ClinicalTrials.gov. At the time clinical trial information is submitted for a voluntarily-submitted clinical trial, a marketing application or premarket notification that includes such triggered trials may or may not have been submitted to FDA; thus, it may not be apparent at the time the voluntarily-submitted clinical trial is submitted to ClinicalTrials.gov which applicable clinical trials are triggered

under section 402(j)(4)(A) of the PHS Act. Therefore, rather than requiring information on the triggered applicable clinical trials to be submitted at the time the clinical trial information is submitted for the voluntarily-submitted clinical trial, we propose in § 11.60(a)(2)(iv)(B), that the information be submitted not later than the date on which the application or premarket notification is submitted to FDA or the date on which clinical trial information is submitted for the voluntarily-submitted clinical trial to ClinicalTrials.gov, whichever is later. This approach would prevent a responsible party from having to submit information for a clinical trial that is not subsequently included in the marketing application or premarket notification. We note that, in many cases, we expect that a triggered applicable clinical trial will have reached its completion date by the time clinical trial information for the voluntarily-submitted clinical trial is submitted because, given the scope of applicable clinical trials subject to 402(j) or the PHS Act, generally, most or all applicable clinical trials for which submission would be triggered by a voluntary submission would have been initiated on or before September 27, 2007, and reached their completion dates prior to December 26, 2007.

Proposed § 11.60(a)(2)(iii) specifies which clinical trial information must be submitted for a triggered applicable clinical trial. Section 402(j)(4)(A) requires that the responsible party submit ''clinical trial information'' for all triggered applicable clinical trials. Because section 402(j)(1)(A)(iv) of the PHS Act defines ''clinical trial information'' to mean ''. . . those data elements that the responsible party is required to submit under paragraph (2) [clinical trial registration information] or under paragraph (3) [clinical trial results information],'' the information required to be submitted for a triggered applicable clinical trial could include registration information, results information, or both. The construction of this requirement mirrors that in section 402(j)(4)(A) of the PHS Act, which specifies that clinical trial information that is voluntarily submitted to ClinicalTrials.gov may consist of registration information or results information. Hence, we propose that the type(s) of clinical trial information required to be submitted for a triggered applicable clinical trial be, at minimum, the same as that for the voluntarily-submitted clinical trial. In other words, if a responsible party voluntarily submits registration information for a clinical trial pursuant to section 402(j)(4)(A) of the PHS Act and proposed § 11.60(a), the responsible party must submit complete registration information specified under proposed § 11.28(a) for any triggered applicable clinical trial(s). Likewise, if a responsible party voluntarily submits results information for a clinical trial pursuant to section 402(j)(4)(A) of the PHS Act and proposed § 11.60(a), then the responsible party must submit complete results information specified under proposed §§ 11.60(a)(2)(i)(B) for any triggered applicable clinical trial(s). Because the submission of clinical trial information for a triggered applicable clinical trial is a condition of voluntary registration under section 402(j)(4)(A) of the PHS Act, the Agency does not propose to treat the submission of such information as a voluntary submission under section 402(j)(4)(A) or proposed § 11.60(a)(2)(ii) that itself could trigger the submission of clinical trial information for other applicable clinical trials. However, as indicated in proposed § 11.60(a)(2)(v), responsible parties who voluntarily submit clinical trial information to ClinicalTrials.gov would be required to update submitted information, including information submitted for triggered trials, in accordance with proposed § 11.64. As noted in section IV.C.5 of this preamble, clinical trial information submitted under proposed § 11.60 will be posted on ClinicalTrials.gov as soon as practicable after it has been submitted and reviewed as part of our quality review procedures. Corrections would be required, in accordance with proposed § 11.66.

We clarify that because section 402(j)(4)(A) of the PHS Act has been in effect since September 27, 2007, any voluntarily-submitted clinical trial submitted on or after September 27, 2007, is subject to the requirements of section 402(j)(4)(A) of the PHS Act. We interpret the relevant marketing application or premarket notification under section 402(j)(4)(A) of the PHS Act to be any marketing application or premarket notification submitted to FDA on or after September 27, 2007. However, we propose that the requirements of proposed § 11.60 apply only to clinical trial information submitted to ClinicalTrials.gov on or after the effective date of this rule. We do not propose to impose the requirements of proposed § 11.60 with respect to any voluntarily-submitted clinical trial or any triggered applicable clinical trial that was submitted under section 402(j)(4)(A) of the PHS Act, prior to the effective date. The Agency is aware that many clinical trials were registered on a voluntary basis at ClinicalTrials.gov before publication of this proposed rule in an effort to comply with other policies (e.g., the policy of the ICMJE), to enhance recruitment, or to enhance transparency related to such clinical trials. To the extent that a responsible party complied with section 402(j)(4)(A) of the PHS Act prior to the effective date of the final rule, we do not believe it is reasonable to require the responsible party to comply with the requirements of proposed § 11.60.

Proposed § 11.60(b) specifies the text of ''a statement to accompany the entry for an applicable clinical trial when the primary and secondary outcome measures for such clinical trial are submitted under [section 402(j)(4)(A) of the PHS Act] after the date specified for the submission of such information in paragraph (2)(C) [clinical trial registration information submission].'' (See section 402(j)(3)(D)(v)(V) of the PHS Act.) Because primary and secondary outcome measures are data elements under both clinical trial registration and results information (See sections 402(j)(2)(A)(ii)(I)(ll) and (3)(C)(ii).), we interpret section 402(j)(3)(D)(v)(V) of the PHS Act to require submissions of registration information or results information under section 402(j)(4)(A) of the PHS Act and/or proposed § 11.60(a) for applicable clinical trials to be accompanied by a statement to clarify that the submission was not subject to the deadlines imposed by section 402(j) of the PHS Act for registration and results information. The required statement would apply to any applicable clinical trial, including any triggered applicable clinical trial, submitted under section 402(j)(4)(A) of the PHS Act and proposed § 11.60(a). Accordingly, the proposed statement is as follows: ''Clinical trial information for this applicable clinical trial was submitted under section 402(j)(4)(A) of the PHS Act and 42 CFR 11.60 and is not subject to the deadlines established by sections 402(j)(2) or (3) of the Public Health Service Act or 42 CFR 11.24 or 11.44.''

2. What requirements apply to applicable clinical trials for which submission of clinical trial information has been determined by the Director to be necessary to protect the public health—§ 11.62

Proposed § 11.62 implements the requirement in section 402(j)(4)(B) of the PHS Act for submission of clinical trial information if the Director determines that the posting of such information on ClinicalTrials.gov is necessary to protect the public health.

Section 402(j)(4)(B)(i) of the PHS Act specifically authorizes the Secretary to ''require by notification'' the submission of clinical trial information ''in any case in which the Secretary determines for a specific clinical trial [. . .] that posting in the registry and results data bank of clinical trial information for such clinical trial is necessary to protect the public health.'' This authority has been delegated to the Director of NIH (74 FR 19973, Apr. 30, 2009). If the Director so determines, clinical trial information must be submitted for that clinical trial in accordance with sections 402(j)(2) and (3) of the PHS Act, except with regard to timing requirements. With respect to timing, such clinical trial information must be submitted to ClinicalTrials.gov ''not later than 30 days after the date specified by the [Director] in the notification,'' unless the responsible party submits a certification for delayed results submission under section 402(j)(3)(E)(iii) of the PHS Act. (See section 402(j)(4)(B)(i)(II) of the PHS Act.) Proposed § 11.62(a) implements this provision by requiring the responsible party for an applicable clinical trial who receives notification pursuant to section 402(j)(4)(B) of the PHS Act that the Director has determined that posting of clinical trial information is necessary to protect the public health to submit such information to ClinicalTrials.gov in accordance with proposed § 11.62(c). We invite public comment on the types of situations in which the posting of clinical trial information might be necessary to protect the public health and on the criteria that the Director should consider when making such a determination.

Proposed § 11.62(b) implements section 402(j)(4)(B)(ii) of the PHS Act, which specifies that the types of clinical trials subject to this provision are limited to those that are: (1) ''an applicable clinical trial for a drug that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act or for a device that is cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved under section 515 or section 520(m) of such Act, whose completion date is on or after the date 10 years before the date of the enactment of the Food and Drug Administration Amendments Act of 2007;'' or (2) ''an applicable clinical trial that is described by both by paragraph (2)(C) and paragraph (3)(D)(ii)(II)) [sic].'' As explained in section III.D of this preamble, we interpret the approval status of a product studied in an applicable clinical trial (i.e., either ''unapproved, unlicensed, or uncleared'' or ''approved, licensed, or cleared'') to be the approval status of the product on any given date. In this context, we interpret the approval status of the product to be the approval status on the date that the Director notifies the responsible party that clinical trial information must be submitted to ClinicalTrials.gov for an applicable clinical trial under proposed § 11.62. The clinical trials specified in (1) would consist of applicable clinical trials of approved, licensed, or cleared drugs (including biological products) or devices that reached their completion dates on or after September 27, 1997. We note that this set of clinical trials would include applicable clinical trials that reach their completion dates on or after the date of enactment of FDAAA, many of which already would be subject to the registration and results submission requirements of section 402(j) of the PHS Act, with the exception of applicable clinical trials that were initiated prior to the date of enactment of FDAAA (i.e., September 27, 2007) and were not ongoing as of December 26, 2007. The clinical trials specified in (2) would consist of applicable clinical trials that are required to register at ClinicalTrials.gov pursuant to section 402(j)(2)(C) of the PHS Act and proposed § 11.22(a) of this part and that study drugs (including biological products) or devices that are unapproved, unlicensed, or uncleared by FDA (regardless of whether or not approval, licensure, or clearance was sought). This set of clinical trials would consist of registered applicable clinical trials that are not required to submit clinical trial results information to ClinicalTrials.gov under section 402(j) of the PHS Act because they are not subject to the results provision in section 402(j)(3)(C) of the PHS Act. However, many of these applicable clinical trials would be required to submit results information under this proposed rule. (See, e.g., proposed § 11.42 and the discussion of effective date implementation in section III.D of this preamble.)

Proposed § 11.62(c) specifies which information must be submitted to ClinicalTrials.gov and the timelines for submitting such information pursuant to a notification from the Director under section 402(j)(4)(B)(i) of the PHS Act. In general, we interpret the references to ''clinical trial information'' in section 402(j)(4)(B)(i) of the PHS Act and submission ''in accordance with paragraphs (2) and (3)'' in section 402(j)(4)(B)(i)(I) of the PHS Act to mean registration information and results information as enumerated in proposed §§ 11.28(a) and 11.48(a). Consistent with section 402(j)(4)(B)(i)(II) of the PHS Act, such information generally must be submitted ''not later than 30 days after the date specified by the [Director] in the notification.'' We are interpreting ''the date specified . . . in the notification'' to mean the date established by the Director for submission of clinical trial information under proposed § 11.62. We note that section 402(j)(4)(B)(i)(II) of the PHS Act permits an exception to the submission deadline if a certification for delayed results submission is submitted not later than 30 days after the submission date specified by the Director in the notification and in accordance with section 402(j)(3)(E)(iii) of the PHS Act. Because a certification under section 402(j)(3)(E)(iii) of the PHS Act would delay only the submission of results information, we propose that if the responsible party has submitted such a certification, only the submission of results information may be delayed. Accordingly, if a responsible party for an applicable clinical trial subject to proposed § 11.62 submits a certification under section 402(j)(3)(E)(iii) of the PHS Act not later than 30 calendar days after the submission date specified in the Director's notification, the responsible party still would be required to submit registration information not later than 30 calendar days after the submission date specified in the notification, although results information would be required to be submitted by the applicable deadline established under proposed §§ 11.44(b) or (c).

To clarify the submission requirement in those situations in which registration information was submitted to ClinicalTrials.gov before a notification under section 402(j)(4)(B)(i)(I) of the PHS Act was sent to the responsible party, we indicate in proposed § 11.62(c)(3) that the registration information must be updated, if necessary, not later than 30 calendar days after the submission date specified in the notification. Notwithstanding this initial update, we propose that the requirements of proposed § 11.64 would apply to clinical trial information submitted pursuant to proposed § 11.62.

All clinical trial information submitted to ClinicalTrials.gov under proposed § 11.62 would be subject to the quality review procedures described in section III.C.12 of this preamble. We would intend to post such information as soon as practicable after it has completed quality review. This timeline for posting would apply to all clinical trial information submitted under

proposed § 11.62, including registration information for an applicable clinical trial of a device that has not previously been approved or cleared by FDA. Section 402(j)(4)(B) of the PHS Act applies equally to applicable clinical trials of drugs and devices that are approved, licensed, or cleared or are unapproved, unlicensed, or uncleared. It applies to ''any case'' in which the Director, as delegated by the Secretary, determines that posting of clinical trial information in ClinicalTrials.gov—not just submission of the information to ClinicalTrials.gov—is necessary to protect public health. Although section 402(j)(4)(B) of the PHS Act specifically allows for a delay in submission of results information if the responsible party submits a certification for delayed results submission under section 402(j)(3)(E)(iii) of the PHS Act, it does not specifically delay or prohibit posting submitted registration information until a device is cleared or approved. We therefore believe that registration information for all applicable clinical trials subject to section 402(j)(4)(B) of the PHS Act may be posted as soon as practicable after it has completed quality review, regardless of the approval, licensure, or clearance status of the devices studied.

We do not interpret the waiver provisions in section 402(j)(3)(H) of the PHS Act or proposed § 11.54 to permit a responsible party to request a waiver of the requirement to submit clinical trial information pursuant to a notification from the Director under section 402(j)(4)(B) of the PHS Act or proposed § 11.62. The waiver provisions in section 402(j)(3)(H) of the PHS Act and proposed § 11.54 apply only to submissions of results information that would be required by section 402(j)(3) of the PHS Act or proposed subpart C. We invite public comment on this proposed interpretation.

3. When must clinical trial information submitted to ClinicalTrials.gov be updated?—§ 11.64

Proposed § 11.64 establishes requirements for updating clinical trial information that has been submitted to ClinicalTrials.gov. Section 402(j)(4)(C)(i) of the PHS Act requires responsible parties for applicable clinical trials to submit updates to ClinicalTrials.gov to reflect changes to previously submitted registration information. Section 402(j)(4)(C)(i)(I) of the PHS Act provides that, in general, updates must be made ''not less than once every 12 months, unless there were no changes to the clinical trial information during the preceding 12-month period.'' Section 402(j)(4)(C)(i)(III) of the PHS Act specifies that the responsible party must update recruitment status not later than 30 days after a change in the recruitment status of a registered applicable clinical trial, and section 402(j)(4)(C)(i)(IV) of the PHS Act specifies that the responsible party must update the completion date not later than 30 days after the completion date of the applicable clinical trial. We believe the shorter update time frames specified for these two elements of registration information in section 402(j)(4)(C) of the PHS Act are intended to help ensure that information in ClinicalTrials.gov of particular importance to prospective human subjects is updated in a timely fashion. Section 402(j)(4)(C)(i)(II) of the PHS Act indicates updates to submitted clinical trial information ''shall include identification of the dates of any such changes.''

In addition, section 402(j)(3)(D)(v)(IV) of the PHS Act requires the Secretary to establish, by regulation, ''the appropriate timing and requirements for updates of clinical trial information.'' Pursuant to this authority, we propose to modify the updating requirements under section 402(j)(4)(C)(i) of the PHS Act. First, we propose to require updates for all clinical trials that are subject to section 402(j) of the PHS Act and/or this proposed rule with a record in ClinicalTrials.gov, not just the applicable clinical trials that are specified in section 402(j)(4)(C)(i) of the PHS Act. This would include those clinical trials for which clinical trial information was voluntarily submitted under section 402(j)(4)(A) of the PHS Act and/or proposed § 11.60 and those for which clinical trial information was required to be submitted to protect the public health under section 402(j)(4)(B) of the PHS Act and/or proposed § 11.62. Second, we propose to require updates for all clinical trial information submitted to ClinicalTrials.gov. This would include the registration information that is referenced in section 402(j)(4)(C)(i) of the PHS Act, the additional registration data elements, and expanded access record information proposed in § 11.28, and results information.

Proposed § 11.64(a)(1) establishes a general requirement for responsible parties to update clinical trial information not less than once every 12 months if there are changes to any of the data elements previously submitted. We emphasize that this requirement to update clinical trial information not less than once every 12 months includes a requirement to update the estimated Completion Date data element, unless there have been no changes in the preceding 12 months. The public should be able to rely upon the accuracy of this date to assist them in determining when results information may be available on ClinicalTrials.gov. In general, we recommend that the complete clinical trial record in ClinicalTrials.gov be reviewed not less than once every 12 months to help ensure that the clinical trial information it contains remains accurate. Proposed § 11.64(a)(2) specifies that updates to clinical trial information must be submitted until the date on which all required clinical trial results information has been submitted to ClinicalTrials.gov, meaning results for all primary and secondary outcome measures and all adverse events collected in accordance with the protocol. After that time, submitted clinical trial information would continue to be subject to the corrections provisions in proposed § 11.66, and responsible parties would be required to submit corrected information when the responsible party becomes aware of any errors or needed corrections in the clinical trial information.

Proposed § 11.64(b) establishes requirements for a responsible party to update certain clinical trial information more rapidly after a change in the status or conduct of a clinical trial or pediatric postmarket surveillance of a device. We recognize that it would be impractical and potentially burdensome to responsible parties to require rapid updates to all clinical trial information data elements each time a change occurs, but section 402(j) of the PHS Act requires more rapid changes of some elements, and we believe that changes to other data elements are sufficiently time-sensitive to require updates more rapidly than once every 12 months.

Proposed § 11.64(b)(1) would require that the following data elements be updated not less than 30 days after a change has occurred:

(1) Study Start Date. We propose that the Study Start Date data element be updated not later than 30 calendar days after the first human subject is enrolled in the clinical trial. This requirement would apply to clinical trials for which an estimated study start date was provided at the time of registration, rather than an actual study start date, i.e., clinical trials that were registered prior to enrollment of the first human subject. The update would ensure that potential human subjects know in a timely fashion that recruitment has begun. It also would ensure that the record reflects the actual start date, as opposed to an estimated start date, and it would provide a mechanism to demonstrate whether a clinical trial had

been registered not later than 21 days after enrollment of the first subject.

(2) Intervention Name(s). We propose that the Intervention Name(s) data element be updated to a non-proprietary name not later than 30 calendar days after a non-proprietary name is established for an intervention studied in a clinical trial. Intervention Name is frequently used as a search term to identify and retrieve clinical trials of interest. If it is not updated for as long as a year, users of ClinicalTrials.gov would not be able to accurately retrieve trials of interest during that time or to easily compare information among multiple trials of the same intervention.

(3) Availability of Expanded Access. We propose that the clinical trial information submitted under the Availability of Expanded Access data element in proposed § 11.10(b)(29) be updated not later than 30 calendar days after an expanded access program is initiated or terminated, or an NCT number is assigned to an expanded access record. This data element informs patients whether access to a drug to treat serious or life-threatening diseases or conditions is available outside of the clinical trial. Expanded access may not be available at the time a clinical trial is registered, and an expanded access program may be terminated on a date other than the completion date of the clinical trial. We therefore propose three specific update requirements:

First, for clinical trials registered on or after the effective date of this regulation, we propose that when an expanded access program for a particular drug is implemented after the clinical trial(s) of that drug is (are) registered, the responsible party must change the indication in proposed § 11.10(b)(29)(i) of whether there is expanded access to the drug not later than 30 calendar days after expanded access becomes available.

Second, we propose that not later than 30 calendar days after the initiation of the expanded access program, the responsible party must create an expanded access record by submitting the data elements required under proposed § 11.28(c), unless an expanded access record for the drug already was already created by another responsible party. The responsible party would be required to enter the NCT number of the expanded access record in the relevant clinical trial record(s) not later than 30 calendar days after the date on which the responsible party receives such NCT number. In the event that there are multiple clinical trials of the same drug that is available through an expanded access program, the responsible party who first changes the Availability of Expanded Access data element from ''yes'' to ''no'' would be required to create the expanded access record under proposed § 11.28(c); once the NCT number is assigned, responsible parties for other clinical trials of that drug would be required to update their clinical trial records by changing the Availability of Expanded Access data element and providing the NCT number. We would expect the sponsor to inform these relevant responsible parties that an expanded access record has been created and provide them with the NCT number.

Third, we propose that if expanded access is terminated, a responsible party must update the Availability of Expanded Access data element not later than 30 calendar days after termination of the program. We note that the expanded access record, including the NCT number, would remain available in ClinicalTrials.gov as archived information. We would expect the sponsor to inform relevant responsible parties that the drug is no longer available through an expanded access program so that the responsible parties may update their clinical trial records accordingly. To help sponsors and responsible parties in this process, we could consider developing procedures to send electronic notification to responsible parties of all applicable clinical trials that list the NCT number of the expanded access record of the discontinued terminated expanded access program.

Consistent with the discussion in the Effective Date/Compliance Date in section III.D of this preamble, the responsible party for an applicable clinical trial that is registered under section 402(j) of the PHS Act and reaches its completion date prior to the effective date of this regulation would be required to update the expanded access program information required under section 402(j)(2)(A)(ii)(II)(gg) of the PHS Act not later than 12 months after a change in the availability of expanded access, as specified in the updating requirement in section 402(j)(4)(C) of the PHS Act. The responsible party of such a clinical trial would not be subject to the requirement to submit the expanded access record data elements listed in proposed § 11.28(c) or to update them as specified in proposed § 11.64. If a responsible party registers an applicable drug clinical trial prior to the effective date of the regulation, however, and such trial is ongoing after the effective date of the regulation, the responsible party would need to submit the necessary expanded access program information by the compliance date for the clinical trial registration information in the databank to comply with proposed § 11.28(c). In addition, the responsible party would be subject to the requirement to provide updates to expanded access program information within 30 calendar days of any change, consistent with proposed § 11.64(b).

(4) Expanded Access Status. We propose that Expanded Access Status, under § 11.28(c)(2)(iv), must be updated not later than 30 calendar days after a change in the status of an expanded access program, whether or not access to the investigational drug or device is currently available. This data element plays a role in expanded access programs that is similar to the role of Overall Recruitment Status in applicable clinical trials, indicating whether a particular expanded access program is still open to participants. We believe that a timely update of any change in status is important to have reflected in the data bank and is consistent with the requirement in section 402(j)(4)(C)(III). Note that we propose to apply this update requirement to expanded access records that are submitted voluntarily (e.g., for an expanded access record submitted for an applicable device clinical trial) as well as to those that are required to be submitted under this part.

(5) Overall Recruitment Status. We propose that the Overall Recruitment Status data element be updated not later than 30 days after a change in the overall recruitment status of the clinical trial. This proposal is consistent with section 402(j)(4)(C)(i)(III) of the PHS Act. We believe that changes in recruitment status should be communicated promptly so that potential human subjects can know whether or not a clinical trial is currently recruiting subjects.

In addition, we propose that if Overall Recruitment Status is updated to ''suspended,'' ''terminated,'' or ''withdrawn,'' the responsible party must at the same time provide information for the Why Study Stopped data element. We believe that suspension, termination, and withdrawal of a clinical trial are significant changes that should be communicated promptly to prospective human subjects, along with the reason for the change. We propose to allow a responsible party to enter this information as free-text so that he or she has flexibility to explain the reason(s) why a clinical trial stopped prematurely. We believe such information is consistent with the statutory objective in section 402(j)(2)(A)(i) of the PHS Act to enable

users ''to track subsequent progress of clinical trials.''

Similarly, we propose that if Overall Recruitment Status is updated to ''terminated'' or ''active, not recruiting,'' the responsible party also must update the Actual Enrollment data element. In either of these situations, recruitment of human subjects is complete. As explained in more detail in section IV.B.4 of this preamble, submission of actual enrollment information will provide users of ClinicalTrials.gov with a mechanism for tracking the progress of registered clinical trials by enabling comparison of the actual enrollment information with the target or estimated enrollment information. More rapid updating is expected to contribute to more accurate reporting of the Actual Enrollment information and to permit users of ClinicalTrials.gov to know more quickly whether the clinical trial achieved its target enrollment.

(6) Individual Site Status. We propose that Individual Site Status be updated not later than 30 calendar days after a change in status of any individual site. We believe this proposal is consistent with the requirement in section 402(j)(4)(C)(III) of the PHS Act. It also supports the purpose of ClinicalTrials.gov to ''enhance patient enrollment'' (See section 402(j)(2)(A)(I) of the PHS Act) by assisting potential human subjects who search for clinical trials by location and wish to retrieve information about only those trials that are open to recruitment in specified locations.

(7) Human Subjects Protection Review Board Status. We propose that Human Subjects Protection Review Board Status be updated not later than 30 calendar days after a change in Human Subjects Protection Review Board Status. Because such information is intended to demonstrate to potential human subjects whether a registered applicable clinical trial or other clinical trial has undergone necessary human subjects protection review board review, has received necessary approvals for human subjects research, or was exempt from such review, we believe it must be updated in a timely fashion.

(8) Completion Date. Pursuant to section 402(j)(4)(C)(i)(IV) of the PHS Act, proposed § 11.64(b) specifies that the Completion Date data element must be updated not later than 30 calendar days after a clinical trial reaches its actual completion date.

(9) Responsible Party, by Official Title. We propose the Responsible Party, by Official Title data element be updated not later than 30 calendar days after a change in either the name of the responsible party of in the responsible party's official title. We believe this update is necessary to enable NIH and other users of the data bank to accurately identify the responsible party for the clinical trial.

(10) Responsible Party Contact Information. Consistent with (9) above, we propose that Responsible Party Contact Information be updated not later than 30 days after a change in the responsible party or the responsible party's contact information. Given that the responsible party must make updates to clinical trial information and, in general, must submit clinical trial results information, we consider it essential to know of changes to the responsible party and to responsible party contact information in a timely manner. Up-to-date information about the responsible party would ensure that the Agency has contact information for the appropriate person responsible for submitting clinical trial information about the applicable clinical trial or clinical trial.

In addition, we propose in § 11.64(b)(2) that responsible parties be required to update the U.S. FDA Approval, Licensure, or Clearance Status data element not later than 15 calendar days after a change in the approval, licensure, or clearance status of the product under study. Products may appear in the market place or manufacturers may announce the pending availability of a product soon after they receive FDA approval, licensure, or clearance. We believe that a prompt update to the information in ClinicalTrials.gov is necessary to help avoid confusing users who seek information about a drug or device in ClinicalTrials.gov after finding the product in the market place (e.g., after being prescribed a new drug) or finding other public information about it (e.g., a news release announcing a new product). In addition, a shorter update period for this data element would enable users to better anticipate when clinical trial results information would be due for an applicable clinical trial. Furthermore, a change in the approval or clearance status of a device can trigger a requirement for the Agency to post previously-submitted clinical trial registration information within 30 days of the change in status. Updating the U.S. FDA Approval, Licensure, or Clearance Status data element not later than 15 calendar days would provide the Agency timely notice that it must post publicly clinical trial registration information.

In § 11.64(b)(3) we propose that relevant clinical trial registration information be updated not later than 30 calendar days after a protocol amendment is approved by a human subjects protection review board, if the protocol is amended in such a manner that changes are communicated to participants in the applicable clinical trial or other clinical trial. We believe that protocol amendments that are communicated to enrolled participants could be important to those considering enrollment and should be communicated quickly through an update to the record in ClinicalTrials.gov. Rapid updating of this information would be consistent with the stated purpose of ClinicalTrials.gov to ''enhance patient enrollment and provide a mechanism to track subsequent progress of clinical trials.'' (See section 402(j)(2)(A) of the PHS Act.) If such key changes were not reflected in the record in ClinicalTrials.gov for as long as 12 months after the change, the value of ClinicalTrials.gov as a source of reliable, accurate information for the public and potential participants in clinical trials would be compromised. We recognize that other thresholds could be used to determine which protocol changes are significant enough to warrant 30-day updating of affected clinical trial information. For example, updating of relevant data elements could also be required any time a protocol amendment is reported to a human subjects protection review board. We invite public comments on our proposed approach and alternatives.

In § 11.64(b)(4), we propose that the Record Verification Date must be updated any time the responsible party reviews the complete set of submitted clinical trial information for accuracy, even if no other updated information is submitted at that time. The record verification date is intended to demonstrate when the information in ClinicalTrials.gov for a particular clinical trial was last checked for accuracy. As noted in section IV.B.4 of this preamble, a responsible party would be required to update the Record Verification Date if he or she examines the complete set of submitted clinical trial information as part of a monthly or annual review, even if he or she determines that no additional or updated information needs to be submitted. Similarly, the responsible party would be required to update the Record Verification Date data element if he or she updates a data element and reviews the rest of the record for accuracy. However, the responsible party would not be required to update the Record Verification date if he or she submits updates to one or more data elements without reviewing the

accuracy of the rest of the record. This proposal would not require a responsible party to review records more frequently or regularly than would be needed in order to update submitted information as otherwise required by proposed § 11.64, but it would require that the Record Verification Date be updated if the complete record were reviewed for accuracy during such an update. Doing so would indicate to users of ClinicalTrials.gov the currency of the information and provide an additional assurance that it is not out-of-date.

In addition, we propose in § 11.64(c) that responsible parties update clinical trial registration information at the time they submit clinical trial results information to ClinicalTrials.gov (unless there are no changes to the clinical trial registration information). This requirement is intended to help ensure the consistency and accuracy of information in the registry and results portions of the data bank. Updated registration information would then be used to pre-populate certain data elements in the clinical trial record so that responsible parties do not have to enter them again. Because the submission and subsequent posting of clinical trial results information is often a reason for users to retrieve the record for a particular clinical trial, the additional update requirement will also ensure that users have access to complete registration and results information that is up-to-date and internally consistent.

We note that the updating requirements under proposed § 11.64 would be prompted by changes in the clinical trial and not by changes in the information submission requirements for ClinicalTrials.gov or the form and manner in which data must be submitted to ClinicalTrials.gov. For example, if clinical trial results information were submitted prior to the effective date of the rule consistent with the requirements of section 402(j)(3)(C) of the PHS Act, the responsible party would not be required as a result of the updating requirements to submit clinical trial results information for the expanded results data elements required under proposed § 11.48. Similarly, if the Agency were to make administrative changes to the manner in which clinical trial information is submitted to ClinicalTrials.gov after the responsible party has submitted clinical trial information in accordance with section 402(j) of this PHS Act and this proposed part, the Agency's revisions to ClinicalTrials.gov would not themselves give rise to a requirement that the responsible party update the applicable clinical trial information. For example, if the Agency added additional options to a drop-down menu for a particular data element, even if one of the additional options would be more appropriate with respect to an applicable clinical trial, the responsible party would not be required to update its previously-submitted clinical trial information, although they could do so voluntarily. However, if a responsible party makes a required update to previously submitted clinical trial information, e.g., to reflect a change in the conduct or progress of a clinical trial, he or she would be required to submit the updated information in the form and manner required by ClinicalTrials.gov at the time the update is submitted. For example, if the set of options in a drop-down menu had changed since the information had previously been submitted, the responsible party would be required to select from the new set of options.

Updates to clinical trial registration information and clinical trial results information will be posted in accordance with proposed §§ 11.35 and 11.52, respectively. Previously submitted clinical trial information will remain publicly available through the ClinicalTrials.gov archive. See proposed § 11.64(d)(1) and (2).

4. What are the requirements for corrections of clinical trial information?—§ 11.66

Proposed § 11.66 sets out requirements for responsible parties to correct clinical trial information submitted to ClinicalTrials.gov. This would include clinical trial information voluntarily submitted under section 402(j)(4)(A) of the PHS Act and/or proposed § 11.60 as well as clinical trial information necessary to protect the public health and submitted under section 402(j)(4)(B) of the PHS Act and/or proposed § 11.62. We consider corrections of information to be different from updates to information, as described in proposed § 11.64. In our view, updates modify clinical trial information to reflect changes in the status or conduct of an ongoing clinical trial or the associated analysis. Corrections revise submitted clinical trial information that is found to be false, invalid, incorrect, inconsistent, or incomplete.

Proposed § 11.66 addresses several types of corrections. First, § 11.66(a) addresses corrections of errors, or misstatement of facts that are found to be incorrect. Errors include, but are not limited to: Inadvertent, typographical errors, such as transpositions of numbers or characters; or inadvertent omissions of data, such as omission of one component of set of participant exclusion criteria. They also include submitted values that are demonstrably wrong, such as an outcome measure indicating more than 24 hours per day of a given value. We expect to detect some such errors during the quality review procedures described in section III.C.12 of this preamble and may identify others in the course of operating the data bank. We intend to inform responsible parties of errors we identify so that they may be corrected. Responsible parties may also detect errors when reviewing submitted information, or they may be alerted to potential errors by other parties. As indicated in proposed § 11.66(a), we would require responsible parties to correct identified errors not later than 15 calendar days after becoming aware of them, whether they identify the errors themselves, or whether we inform them of errors we have detected, such as through our quality assurance procedures, whichever is earlier.

Second, § 11.66(b) addresses corrections to information that is falsified or based on falsified information. Consistent with FDA's proposed use of the term ''falsification of data'', we consider ''information that is falsified or based on falsified information'' to mean information that was created, altered, recorded, or omitted in such a way that the data do not represent what actually occurred in the clinical trial. (See 75 FR 7414, Feb. 19, 2010.) Examples of information that are falsified or based on falsified information include, but are not limited to, the following (based on examples in 75 FR 7414, Feb. 19, 2010):

(1) Created information that was never obtained (e.g., the values submitted for a primary outcome measure were made up or based on participant-level data that were made up; the actual enrollment value submitted includes subjects who did not exist or were not actually enrolled in the clinical trial).

(2) Information that was altered by replacing original information with something different that does not accurately reflect study conduct or results (e.g., the value submitted for a baseline characteristic is changed to a less extreme deviation from normal or is based on individual measures of the baseline characteristic that were changed be less extreme deviations from normal).

(3) Information that was recorded or obtained from a human subject in a way that does not accurately reflect the study protocol (e.g., a submitted outcome measure is based on measurements from subjects who were given a different dose

of an experimental drug than that specified in the protocol and the ClinicalTrials.gov record).

(4) Omitted information that was obtained and would be appropriate for submission based on study design and conduct (e.g., values are not submitted for a secondary outcome measure for which data were collected during the clinical trial or the values submitted for the secondary outcome measure do not include outcomes that were measured on some subjects so the analysis yields a result that would not have been obtained had all data been analyzed).

As specified in proposed § 11.66(b), we would require a responsible party to inform the Director when a sponsor determines that information submitted to ClinicalTrials.gov was falsified or based on falsified information. The responsible party would be required to inform the Director about falsification at the same time as he or she submits corrected information or informs the Director that either correct information cannot be generated or previously submitted information is correct (i.e., the falsification did not result in incorrect information being submitted to ClinicalTrials.gov). If corrected information can be generated, we would require the responsible party to submit corrected information not later than 15 calendar days after it becomes available. If it is determined that submitted information cannot be corrected or is correct as previously submitted we would require the responsible party to notify the Director not later than 15 days after such a determination is made. For a clinical trial for which corrected data cannot be generated, we would indicate in ClinicalTrials.gov that data for such clinical trial were determined to be falsified or based on falsified information and that corrected information is not available. Such an indication would inform users of ClinicalTrials.gov of the status of the information in the record for that clinical trial. For a clinical trial for which the falsification of data does not affect the information submitted to ClinicalTrials.gov (e.g., because underlying falsified data did not contribute to the analysis of outcomes), we would not include an indication of falsification on the ClinicalTrials.gov record. Information about findings of falsification might be included in published journal articles for which Medline citations are linked from the record, in FDA information that is linked from the record, or in other publicly available information.

We recognize that, in some cases, after determining that submitted information was falsified or based on falsified information, it may take time for a responsible party to assess whether or not the information submitted to ClinicalTrials.gov was affected, determine whether any affected information can be corrected, and generate corrected information, as needed. For example, the results of the clinical trial may need to be reanalyzed after excluding data that have been falsified and the results of such reanalysis compared with previously submitted data. Under our proposal, a responsible party would be required to notify the Director of falsification only after he or she had assessed whether or not the falsification resulted in incorrect data being submitted to ClinicalTrials.gov, determined whether corrected information could be generated, and generated any needed corrections to the data. We considered, but do not include in this proposed rule, a requirement for a responsible party to provide earlier notification to the Director of a determination that information submitted to ClinicalTrials.gov had been falsified or was based on falsified information (e.g., such notification could be provided not later than 15 days after the determination is made). Following such a proposal, the responsible party would then have been required either to make a second notification stating whether the submitted information was correct as submitted or unable to be corrected or to submit corrected information. We invite public comment on the advantages and disadvantages of this alternative approach, including on the amount of time that might typically pass between determining that data have been falsified and determining whether submitted clinical trial information can be corrected or does not need correction. We specifically invite comment on the implications of the proposed approach in cases when that time period may be lengthy. We also invite comment on what, if any, information might be made make publicly available in ClinicalTrials.gov in these situations. We invite comments on all other aspects of our proposal, as well.

Third, § 11.66(c) addresses corrections necessary to address various other deficiencies in submitted information. Such deficiencies include but are not limited to inconsistencies in submitted data, for example, a mismatch between the reported number of subjects enrolled in a clinical trial and the sum of reported number of subjects assigned to different arms, and incomplete entries that are insufficient to convey their intended meaning, such as a description of an outcome measure that does not describe the measurement scale being used. We believe that requiring corrections of such information is necessary step in ensuring that the information contained in ClinicalTrials.gov is not false or misleading. We expect to identify some needed corrections during the quality review procedures described in section III.C.12 of this preamble and in the course of operating the data bank. As with errors, we plan to inform responsible parties of these needed corrections. We expect that responsible parties may also become aware of needed corrections through their own reviews of submitted data or from other parties. Proposed § 11.66(c) provides that responsible parties who become aware of needed corrections or are informed by NIH of needed corrections to clinical trial information submitted under §§ 11.28, 11.48, or 11.60 must submit corrected information as soon as possible, but not later than 15 calendar days after the date that they become aware of the need for correction or that NIH informs them of the needed correction, whichever is earlier.

Compliance with our quality control process, including the requirements set forth in § 11.66, does not necessarily constitute a legal defense to enforcement pursuant to section 301(jj) of the FD&C Act (21 U.S.C. 331) and 303(f) of the FD&C Act (21 U.S.C. 333(f)).

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the Dates section of this preamble, and will respond generally to the comments in the preamble to any subsequent rulemaking document.

VI. Regulatory Impact Statement

The Agency has examined the impacts of this proposed rule under Executive Order 12866, Regulatory Planning and Review, Executive Order 13563, Improving Regulation and Regulatory Review, the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), the Unfunded Mandates Reform Act of 1995 (Public Law 104–4), and Executive Order 13132, Federalism. Executive Order 12866, as amended by Executive Order 13563, directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize

net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any single year). The Agency estimates that the total cost of the proposed requirements to regulated entities is approximately $49.7 million annually. We believe there are intangible benefits, in the form of increased public trust in clinical research and improvements in human subjects protection, clinical care, clinical research, and product development that may result from enhanced access to clinical trial results. We believe that this proposed rule is not an economically significant regulatory action as defined by Executive Order 12866. Because of the interest in this proposed rule among regulated entities and others involved in conducting or using the results of clinical trials, we have nevertheless prepared an analysis that, to the best of our ability, estimates the costs and benefits of this proposed rule. We request comments on the economic analyses provided in this proposed rule.

The RFA requires agencies to analyze regulatory options that would minimize any significant impact of a rule on a substantial number of small entities. Because the rule is likely to impose estimated costs of approximately $6,700 per applicable clinical trial on organizations that conduct applicable clinical trials, the Agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires, among other things, that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' (See 2 U.S.C. 1352(a)) The current threshold after adjustment for inflation is $141 million, based on the Gross Domestic Price deflator for 2012. The Agency does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount. As explained above, however, the Agency has conducted an analysis of the costs that could result from this proposed rule.

Executive Order 13132 (Federalism) 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.

A. The Proposed Rule

This proposed rule would implement the provisions for the mandatory registration and submission of results information for applicable clinical trials at ClinicalTrials.gov, as required by section 402(j) of the PHS Act (42 U.S.C. 282(j)), added by section 801 of FDAAA. This proposed rule would both clarify the statutory requirements for submission of registration and results information, including adverse events information, and implement the expansion of the registry and results data bank by rulemaking as required by section 402(j)(3)(D) of the PHS Act.

B. Need for the Proposed Rule

The Agency is promulgating this proposed rule to fulfill the requirements of section 402(j) of PHS Act in a manner that will provide broad public access to pertinent clinical trial registration and results information. Section 402(j)(2)(A)(i) of the PHS Act requires the Secretary to expand the clinical trials registry data bank with respect to clinical trial information to ''enhance patient enrollment and provide a mechanism to track subsequent progress'' of the clinical trials. Sections 402(j)(3)(B) and 402(j)(3)(C) of the PHS Act instruct the Secretary to expand the clinical registry data bank not later than 1 year after enactment of FDAAA to include the results information specified in section 402(j)(3)(C) for certain applicable clinical trials. Section 402(j) of the PHS Act also requires responsible parties to submit to the expanded data bank specified registration information (i.e., descriptive information, recruitment information, location information, and administrative information) summarizing key aspects of applicable clinical trials that are subject to the law and specified results information describing the outcomes of applicable clinical trials for which the drugs or devices under study have been approved, cleared, or licensed by FDA. Section 402(j) of the PHS Act further establishes deadlines by which such information must be submitted and establishes penalties for non-compliance. This proposed rule is intended, in part, to implement the statutory requirements and clarify the Agency's interpretation of them. It clarifies the meaning of terms defined in the PHS Act (e.g., responsible party and applicable clinical trial) and of several data elements that are required to be submitted to the data bank (e.g., study design, eligibility criteria). It also exercises the authority given to the Secretary in section 402(j)(2)(iii) of the PHS Act to modify by regulation the requirements for clinical trial registration information. This proposed rule specifies several modifications to the clinical trial registration information that the Agency believes meet the statutory criteria of improving and not reducing the statutorily specified clinical trial registration information.

In addition, this proposed rule is necessary to implement provisions of section 402(j) of the PHS Act that are specifically required to be addressed by regulation. Section 402(j)(3)(I) of the PHS Act, requires the Secretary to determine by regulation the ''best method'' for including in the registry and results data bank appropriate results information on serious adverse and other adverse events collected for certain applicable clinical trials. Section 402(j)(3)(D) of the PHS Act requires, among other things, the Secretary to further expand the registry and results data bank through rulemaking to ''provide more complete results information and to enhance patient access to and understanding of the results of clinical trials.'' That section of the PHS Act specifies several topics that the rule is to address, including: Whether to require the submission of results information for applicable clinical trials of drugs and devices that previously have not been approved, licensed, or cleared by FDA; whether technical or lay summaries of a clinical trial can be included in the data bank without being misleading or promotional; and whether to require responsible parties to submit the full protocol or ''such information on the protocol . . . as may be necessary to help evaluate the results of the trial.'' This proposed rule addresses each of these topics and others specified in section 402(j) of the PHS Act.

C. Benefits of the Proposed Rule

As discussed in this preamble, the overarching aim of this proposed rule is to provide public access to a standardized set of non-technical and technical information describing the conduct and results of certain clinical trials of FDA-regulated drugs (including biological products) and devices. Access to this information will benefit not only the general public, but also other groups of people involved in improving public health. These groups of people include potential and enrolled clinical trial participants, clinical researchers, systematic reviewers, disease and

patient advocacy groups, regulators, drug and device manufacturers, health care providers, patients and their family members. Access to information contained in the data bank is intended to enhance patient enrollment in clinical trials and improve the evidence-base that informs clinical care, enhance public health and safety, increase the efficiency of drug and device development processes, and improve clinical research practice, among other uses. It is also intended to build public trust in clinical research by providing public access to the results of such research. These benefits are intangible.

D. Costs Associated With the Proposed Rule

The costs associated with this proposed rule consist of the time and effort necessary for responsible parties to comply with the proposed requirements to register applicable clinical trials; submit specified results information (including adverse event information); update and correct submitted registration and results information, as needed; submit certifications and/or extension requests to delay the deadline for submitting results information; submit information describing expanded access programs for drugs studied in an applicable clinical trial, and request waivers to any of the requirements for results submission. We do not intend this proposed rule to cause responsible parties to collect any information that was not already intended to be collected during the clinical trial (as described by the study protocol), nor do we intend this proposed rule to cause responsible parties to analyze such information in ways that were not intended, as described in the protocol or the associated statistical analysis plan. Rather, the rule specifies those elements of the collected results information and statistical analyses that must be submitted to the data bank and the format in which they must be submitted.

The calculations below present our estimates of the time and cost associated with meeting the information submission requirements of this proposed rule, including the burden associated with assembling the required information, formatting the information for submission, submitting it to the data bank, and correcting or updating it over time. The calculations break out the estimated annual costs associated with: (1) registering a trial, (2) submitting results information (including adverse event information), (3) submitting certifications, extension requests and appeals to delay the results submission deadline, (4) submitting clinical trial information that is triggered by a voluntary submission; and (5) creating expanded access records for drugs studied in an applicable clinical trial. The estimates include the costs associated with updating submitted information and with correcting errors detected by NIH. We estimate the total annual cost to be $49,713,753. As explained below, we expect that during the first year after the effective date of this proposed rule, responsible parties will incur some additional time and cost to update clinical trial information that previously was submitted to the data bank for trials that were initiated prior to the effective date and ongoing as of that date. We estimate this additional, non-recurring cost to be $2,457,080.

We expect that over time the cost of complying with this proposed rule will decline notably once a final rule is published and responsible parties become more familiar with the registration and results submission requirements as well as the data submission and review processes. Many data providers have developed standard operating procedures for data entry personnel and refined their data management systems to facilitate data submission. A number of clinical trial data management software tools currently allow users to output registration information for automatic uploading of files in bulk to ClinicalTrials.gov. We expect that once the requirements for submission of clinical trial information are clarified, responsible parties will automate portions of the data extraction and formatting processes for required results information, significantly reducing the burden of compliance with this proposed rule.

TABLE 2—ESTIMATED ANNUAL COST OF PROPOSED RULE

Provision	Proposed section(s)	Estimated annual cost prior to rulemaking	Estimated annual cost under the proposed rule	Incremental cost above pre-rule data collection
Registration of applicable clinical trials, including updates	11.28(a),(b), 11.64	$11,005,132	$11,483,616	$478,484
Results submission for applicable clinical trials, including updates.	11.48, 11.64	6,444,954	37,828,800	31,383,846
Submission of certifications, extension requests, and appeals to delay results submission.	11.44(b), (c), (e)	189,783	261,990	72,207
Triggered registration and results submission following voluntary submissions.	11.60	0	129,260	129,260
Submission of expanded access records	11.28(c).	0	10,087	10,087
Total		17,639,869	49,713,753	32,073,884

1. Registration of Applicable Clinical Trials

To estimate the costs of trial registration, we first estimated the number of applicable clinical trials that would be initiated in a given year and be subject to the provisions of this proposed rule. Using the approach described below, we estimate that a total of 7,400 applicable clinical trials of drugs (including biological products) and devices per year would be subject to the registration requirement of this proposed rule. This estimate is based on information from FDA indicating that it receives approximately 5,150 clinical trial protocol submissions annually for applicable clinical trials (76 FR 256, Jan. 4, 2011). This figure includes protocol submissions to CDER, CBER, and CDRH; it does not include clinical trials that were not conducted under an IND or IDE. To estimate the number of such clinical trials, we examined the number of clinical trials registered with ClinicalTrials.gov that appear to meet the criteria of an applicable clinical trial but do not appear to have been conducted under an IND or IDE, e.g., because they are exempt. We found approximately 1,700 and 2,000 such clinical trials in 2012 and 2013, respectively. We increased this figure to 2,250 to accommodate further growth in the number of such clinical trials that would be registered following

publication of the final rule. The sum of these figures (i.e., 5,150 plus 2,250 equals 7,400) provides an estimate of the number of applicable clinical trials that would be subject to the registration requirement of this proposed rule each year.

To calculate the burden associated with registering these clinical trials, we estimated the time required to submit complete clinical trial registration information for an applicable clinical trial. We estimate this time to be 8 hours, including time to extract information from the study protocol, reformat it, and submit it to ClinicalTrials.gov. This figure is one hour more than the estimate used in the existing OMB Paperwork Reduction Act clearance for the ClinicalTrials.gov data collection (77 FR 22579, Apr. 16, 2012) to account for the additional data elements that would be required by this proposed rule. Applying this time estimate to the estimated number of applicable clinical trials yields a burden of 59,200 hours per year for registering applicable clinical trials. Based on our previous experience, we estimate that each registration record would be updated an average of 8 times during the course of the study (e.g., to reflect changes in the conduct of the clinical trial, additions of investigational sites, recruitment status updates). Although clinical trials of long duration and with multiple sites would likely submit more updates during the course of the trial, we have found that many applicable clinical trials have a relatively short duration and a limited number of study sites, which lowers the average per clinical trial. The time required for subsequent updates of clinical trial registration information is expected to be significantly less than for the original registration (as less information must be provided) and is estimated to be 2 hours per update. Using these figures, we calculated the annual hour burden for updates to clinical trial registration information to be 118,400 hours. Combining this figure with the estimated time for initial registrations (59,200 hours) yields an estimate of the total hour burden associated with the submission and updating of clinical trial registration information of 177,600 hours per year.

To calculate the cost of registration, we examined May 2011 data from the U.S. Bureau of Labor Statistics on the average wages of workers in the pharmaceuticals and medical equipment industries who are involved typically in submitting registration information. During the time we have operated ClinicalTrials.gov, we have found that this task is generally performed by junior-level researchers or administrative staff. For purposes of this estimate we used an average hourly wage rate of $32.33, which is equivalent to the weighted 25th percentile wage of a medical scientist in the pharmaceutical and medical equipment industries and is significantly higher than the median wage of other administrative staff in those sectors who sometimes submitting registration information to ClinicalTrials.gov. We doubled these wage figures (to $64.66 per hour) to account for benefits and overhead. Using this adjusted wage figure, we calculated an estimated total annual cost of registration under the proposed rule, including updates over the course of a clinical trial, of $11,483,616 (Table 2). This figure represents an incremental increase of $478,484 per year above the estimated cost of registration under the existing OMB Paperwork Reduction Act clearance for the ClinicalTrials.gov data collection.

2. Results Submission

To estimate the burden associated with submission of clinical trial results information, we start from the premise that every clinical trial required to register in a given year would be required subsequently to submit results information. The statute requires results submission for all applicable clinical trials that study drugs (including biological products) or devices that are approved, cleared, or licensed by FDA; the proposed regulation would require, in addition, the submission of clinical results information for applicable clinical trials of drugs (including biological products) and devices that are not approved, cleared, or licensed by FDA. We therefore estimate the burden associated with results submission for a total of 7,400 applicable clinical trials of drugs (including biological products) and devices per year, recognizing that in most cases, such clinical trial results information would not be submitted in the same year as the associated clinical trial registration information but in accordance with the deadlines specified in proposed § 11.44. We expect, however, that on average the number of clinical trials for which clinical trial results information is submitted in any given year would approximate the number of new trials for which clinical trial registration information is submitted.

To estimate an average amount of time required to submit clinical trial results information, we reviewed a variety of data sources, including publicly available information from various organizations about results submission times [Ref. 45], comments made at the April 2009 public meeting (Ref. 1), responses to the burden estimates included in the current and previous OMB clearance documents (77 FR 22579, Apr. 16, 2012; 73 FR 58972, Oct. 8, 2008), feedback from respondents who tested preliminary versions of the data entry system during the summer of 2008, and feedback from those submitting data to the existing ClinicalTrials.gov system. These sources contain a wide-range of estimates, from as little as 6 hours to as long as 60 hours. We believe the differences in these estimates reflect a number of factors, including the significant variation in the complexity of applicable clinical trials, in terms of their study design, number of outcome measures (primary and secondary), statistical analyses, and adverse event information. They also reflect differences in the responsible party's familiarity with the clinical trial results information and the ClinicalTrials.gov submission process and the time they attribute to assembling the information for submission. Shorter estimates may be indicative of situations in which the responsible party already has assembled (and analyzed) the clinical trial results information for purposes of preparing a journal article or other summary report, while longer estimates may assume the clinical trial results information needs to be compiled. We expect that in most situations, the responsible party would have ready access to the necessary information because it is information that the clinical trial is conducted to collect and analyze (i.e., the information we propose for submission would have been collected during the trial, as specified in the protocol). Nevertheless, for purposes of this analysis, we selected an average time of 40 hours for initial submission of clinical trial results information, which corresponds to the higher range of estimates contained in several industry surveys and in other comments the Agency received. This figure represents an increase of 15 hours over the 25-hour estimate that was included in the most recent OMB Paperwork Reduction Act clearance for the ClinicalTrials.gov data collection and reflects the additional information that would be required to be submitted under this proposed rule. We expect the hour burden would decline as responsible parties become more familiar with ClinicalTrials.gov and implement procedures for streamlining data collection, analysis, and formatting. In the most recent OMB Paperwork Reduction Act clearance for the current ClinicalTrials.gov data collection, we

estimated that results information would be submitted for 1,845 applicable clinical trials per year, which is the estimated number of clinical trials that would have been included in marketing applications for drugs, biological products, and devices that were initially approved, licensed, or cleared by the FDA and subject to the basic results reporting provisions of FDAAA. Under this proposed rule, results information would be required for all applicable clinical trials that were subject to the registration requirement (i.e., an estimated 7,400 clinical trials per year). Applying the 40-hour figure to 7,400 applicable clinical trials per year produces a total estimated burden of 296,000 hours per year for submitting clinical trial results information. This figure compares to an estimated 46,125 hours under the current information collection.

We also estimate that, on average, each results record would be updated twice after the initial submission to reflect changes in data analysis or the submission of additional results from other pre-specified outcome measures. We estimate that each such update would take 10 hours, on average. This figure is 2 hours higher than the 8-hour estimate used in the OMB Paperwork Reduction Act clearance for the current ClinicalTrials.gov data collection and reflects ongoing experience with data submission to ClinicalTrials.gov. Applying these estimates to 7,400 applicable clinical trials per year produces an estimate of 148,000 hours per year for updates to clinical trial results information (two updates per trial), compared to 29,520 hours for the 1,845 applicable clinical trials estimated under the existing information collection. Combining the figure for updates with the estimate of the initial burden of submitting clinical trial results information, produces a total estimated annual hour burden for results submission under the proposed rule of 444,000 hours, compared with 75,645 hours under the existing information collection.

To calculate the economic cost of clinical trial results submission, we examined the average wages of workers in the pharmaceuticals and medical equipment industries who typically are involved in submitting clinical trial results information. Based on our experience in operating the results database and our consultations with data submitters, we believe that this task is performed generally by clinical researchers who are more experienced than those involved in registration. Based on May 2011 data from the U.S. Bureau of Labor Statistics, we use an average hourly wage rate of $42.60, which corresponds to the weighted median hourly wage of a medical scientist in the pharmaceutical and medical equipment manufacturing industries. We doubled this wage rate (to $85.20 per hour) to account for benefits and overhead. Using this adjusted wage rate, we estimate a total annual cost of results submission under this proposed rule, including updates, of $37,828,800 (Table 2). This represents an increase of $31,383,846 per year above the estimated $6,444,954 cost of results submission under the current information collection.

3. Delayed Submission of Results via Certification or Extension Request

We also have estimated the average time and cost associated with the submission of certifications and extension requests to delay results submission, consistent with proposed §§ 11.44(b), (c), and (e). Responsible parties for applicable clinical trials may submit a certification to delay results submission provided that initial approval or approval of a new use is sought. We estimate that the number of clinical trials that would qualify for delayed submission of results in a given year would not exceed the estimated number of newly initiated applicable clinical trials per year that are conducted under an IND or IDE. Such clinical trials would study drugs and devices that are unapproved, unlicensed, or uncleared or that are approved, licensed, or cleared but are studied for possible new uses. While some responsible parties might elect to submit clinical trial results information 1 year after the completion date instead of delaying submission via a certification, for purposes of this estimate, we assume that they all will elect to submit a certification to delay results submission. (Note that the subsequent burden of submitting clinical trial results information is captured by the calculations in section 2 above). Using the same FDA data as was used to estimate the number of applicable clinical trials subject to the registration requirements of this proposed rule, we estimate that certifications would be submitted for 5,150 trials per year. We estimate that it would take no more than 30 minutes for a responsible party to determine that a clinical trial is eligible for a certification (and to verify the eligibility with a sponsor or manufacturer, if necessary) and to submit the necessary information through ClinicalTrials.gov. Using this figure produces an estimated annual hour burden of 2,575 hours for certifications. We estimate that the hourly wage of personnel who would submit the certification is the same as that for submitting clinical trial results information, or $42.60. Doubling this wage rate to account for benefits and overhead produces an annual estimated cost of $219,390 per year.

For good-cause extension requests, we estimate that approximately 200 requests will be submitted each year. This estimate is based on several considerations, including the rate of submission of requests between September 2008 and September 2010, when some 70 extension requests were submitted to ClinicalTrials.gov. In many cases, responsible parties did not need to submit an extension request in order to delay results submission; many of the submitted extension requests indicated that the estimated completion date of the applicable clinical trial had changed or that the clinical trial was not an applicable clinical trial subject to section 402(j) of the PHS Act. We would not expect an extension request to be submitted in these situations; rather, we would expect responsible parties to update their estimated completion date to reflect changes in the progress of the trial or to use the approach described in proposed § 11.22(b) and section IV.B.2(b) of this preamble to determine that the clinical trial is not an applicable clinical trial that is subject to this proposed rule. Excluding such unnecessary requests and considering only those submitted for applicable clinical trials for which the actual completion date had passed, we received approximately 20 requests per year. We expect that the number of extension requests will increase once a final rule is published and responsible parties have more clarity about the deadlines for submitting clinical trial results information. The estimated 200 extension requests per year represent a 10-fold increase over the annual rate of submissions to date and would be equivalent to four percent of all applicable clinical trials for which clinical trial results information is to be submitted in a given year (i.e., 200 out of 5,500). It would also represent more than 10 percent of the applicable clinical trials that do not delay results submission via certification. While responsible parties may request an extension request even after they have filed a certification, we expect this would happen infrequently. Moreover, as explained in section IV.C.3(d) of this preamble, we expect that extensions will be granted in only a limited set of circumstances where ''good cause'' has been demonstrated. In those cases in which an extension request is denied,

the responsible party would have the opportunity to appeal the denial. If we estimate that 50 percent of extension requests are denied and that 50 percent of denials result in an appeal, the number of appeals per year would total 50.

We estimate that the time required gathering the information required for a good-cause extension request or appeal and submitting it to ClinicalTrials.gov would be no more than 2 hours. Using this figure, we estimate that the annualized hourly burden for extension requests and appeals would be 500 hours. We expect that requests will be submitted by those familiar with the results submission requirements and therefore use an hourly wage of $42.60. Doubling this wage rate (to $85.20) to account for benefits and overhead brings the annualized cost of extension requests to $42,600. Combining the estimated costs for certification and extension requests produces a total cost of $261,990 per year (Table 2). The most recent OMB Paperwork Reduction Act clearance for the ClinicalTrials.gov data collection estimated that 3,655 certifications would be submitted by responsible parties seeking initial approval or approval of a new-use of a drug, biological product, or device studied in an applicable clinical trial and that 200 extension requests would be submitted per year. These figures would yield an estimated annual cost of $189,783, meaning that the incremental cost attributable to this rule would be $72,207 per year.

4. Triggered Submission of Clinical Trial Information Following a Voluntary Submission

Proposed § 11.60 implements section (402(j)(4)(A) of the PHS Act and indicates that if a responsible party voluntarily registers or submits results information for a clinical trial of an FDA-regulated drug or device that is not an applicable clinical trial subject to the mandatory clinical trial information submission requirements under the proposed part, that responsible party must, under specified circumstances, also submit information for other applicable clinical trials that are included in a marketing application or premarket notification that is submitted to FDA and for which clinical trial information has not already been submitted to ClinicalTrials.gov. The types of trials for which the voluntary submission of clinical trial information would invoke this requirement would include, e.g., phase 1 trials of drugs, small feasibility studies of devices (neither of which are considered to be applicable clinical trials), or applicable clinical trials that are not otherwise subject to section 402(j) of the PHS Act because they were initiated prior to the date of enactment of FDAAA and were no longer ongoing as of December 26, 2007. The voluntary submission of clinical trial information for such trials would trigger a requirement to submit clinical trial information for other applicable clinical trials that are included in the marketing application for a drug or device, as long as the entity submitting the marketing application or premarket notification is the same as the responsible party for those other trial and still has access to and control over the necessary data.

In practice, we expect that the requirement under section 402(j)(4)(A) of the PHS Act to submit clinical trial information for applicable clinical trials not otherwise registered in ClinicalTrials.gov would be triggered infrequently. In most cases, when clinical trial information is submitted voluntarily, we expect that the applicable clinical trials required to be submitted in a marketing application that includes the voluntarily-submitted clinical trial would have been required to be registered in ClinicalTrials.gov under section 402(j)(2)(C) of the PHS Act and this proposed part. For example, the voluntary submission of information for a phase 1 trial of an unapproved drug would trigger the submission of information for an applicable clinical trial only if that phase 1 trial were included in a marketing application that also included an applicable clinical trial (e.g., a phase 2 clinical trial) that was not otherwise required to submit clinical trial information to ClinicalTrials.gov (e.g., because it completed before September 27, 2007), and if the responsible party of the voluntarily-submitted trial were the same as the entity submitting the marketing application. For these reasons, we do not anticipate many clinical trials that are submitted voluntarily after the date of enactment of FDAAA to be associated—through an FDA marketing application—with applicable clinical trials that pre-date FDAAA. For purposes of this analysis, we estimate that 1 percent of the clinical trials registered voluntarily with ClinicalTrials.gov each year could trigger the submission of clinical trial information for an applicable clinical trial for which clinical trial information was not otherwise required to be submitted to ClinicalTrials.gov. Of the 17,000 clinical trials that are registered every year, on average, with ClinicalTrials.gov, we estimate that 9,600 are voluntary submissions (all but the 7,400 that are applicable clinical trials). Using this figure, voluntary registrations would trigger the required submission of clinical trials information for an estimated 96 clinical trials per year. Based on our experience to-date with voluntary submissions, we expect that for at least three-quarters of those triggered trials (72), registration information only would need to be submitted; for the other quarter, results information would need to be submitted. For those clinical trials for which only registration information is required, we estimate that it would take 8 hours to register the clinical trial by a data submitter with an average hourly wage rate of $32.33 (consistent with the figures used for registration of applicable clinical trials). Doubling the wage rate to account for benefits and overhead produces an estimated cost of $37,244 per year. Submitted information would not generally need to be updated because the clinical trial would, in general, have reached its completion date by the time the requirement to submit clinical trial information is triggered and there would be few, if any, updates to report. For the remaining quarter of the triggered clinical trials (24) we estimate that the hourly burden would equal the 40 hours estimated for results submission for other applicable clinical trials plus 5 hours to account for the additional data elements that are specified in proposed § 11.60(a)(2)(i)(B). Using these figures and doubling the estimated average hourly rate of $42.60, we estimate the annual cost of submission as $92,016. Combining this figure with the $37,244 figure for triggered clinical trials that submit only registration information, produces a total annual estimated cost for the submission of clinical trial information triggered by the voluntary submission of information under proposed § 11.60 of $129,260 (Table 2). Because the submission of clinical trial information triggered by the voluntary submission of information was not included in the most recent OMB Paperwork Reduction Act clearance for the ClinicalTrials.gov data collection, the incremental cost attributable to this rule would be the full estimated cost of $129,260 per year.

We note that a number of voluntary submissions of clinical trial information would likely be made to ClinicalTrials.gov each year. Responsible parties often register clinical trials voluntarily in order to assist in the recruitment of subjects or so that they may publish any resulting scientific papers in leading peer-reviewed scientific journals. Because such clinical trials are not required to be

registered or to submit results information under section 402(j) of the PHS Act, we do not include them in this cost estimate. Because such information is submitted voluntarily to ClinicalTrials.gov, we do account for voluntary submissions in the estimates for Paperwork Reduction Act clearance. See section VII below.

5. Expanded Access Records

As specified in proposed § 11.28(a), if expanded access is available under section 561 of the Federal Food, Drug, and Cosmetic Act to a drug that is studied in an applicable drug clinical trial, the responsible party must include the NCT number of an expanded access record with the clinical trial information submitted at the time of registration. If an expanded access record for the drug has not yet been submitted to ClinicalTrials.gov, the responsible party must create an expanded access record by submitting the data elements listed § 11.28(c). To determine the cost and burden associated with the creation of this record, we relied on information from the FDA that estimates that 10 treatment INDs or treatment protocols and 68 expanded access programs for treatment of an intermediate size patient population are initiated annually. These are the two types of expanded access programs for which the information listed in § 11.28(c) must be submitted to ClinicalTrials.gov under this proposed rule (i.e., as explained in section IV.an expanded access record is not required if expanded access is available for treatment of an individual). We estimate the time required to submit the required information for an expanded access record to be 2 hours, which is one-quarter of the estimated time to register an applicable clinical trial. An expanded access record requires only about one-half of the data elements required for an applicable clinical trial (22 versus 39) and does not require some of the more detailed data elements, such as Primary Outcome Measure, Secondary Outcome Measure, Individual Site Status, and Facility Location information. We therefore estimate the total hour burden associated with expanded access records to be 156 hours per year. We expect that expanded access records are submitted by staff with the same qualifications as those registering applicable clinical trials and, hence use an estimated hourly wage of $32.33. Doubling this wage rate (to $64.66) to account for benefits and overhead results in a total estimated annual cost of $10,087 (Table 1). Because the submission of expanded access records was not included in the most recent OMB Paperwork Reduction Act clearance for the ClinicalTrials.gov data collection, the incremental cost attributable to this rule is the full estimated cost of $10,087 per year.

6. Non-Recurring Cost of Bringing Previously Submitted Registration Information Into Compliance With This Proposed Rule

As discussed in section III.D of this preamble (''Effective Date''), we expect that a responsible party for any applicable clinical trial for which results information would be required to be submitted to ClinicalTrials.gov after the effective date of this rule would have to update any previously submitted clinical trial registration information by the compliance date to meet the requirements of proposed § 11.28. The responsible party would need to submit any data elements specified in proposed § 11.28(a)) that were not submitted at the time the trial was registered and make sure the entries for all required data elements include the complete set of information defined in proposed § 11.10(b) (e.g., include all the specified elements of Study Design).

To estimate the number of clinical trials that might require such updates, we searched ClinicalTrials.gov for clinical trials that were registered after the enactment of FDAAA (i.e., September 27, 2007) and appeared to meet the definition of an applicable clinical trial. We found nearly 3,700 such clinical trials registered each year. Of those clinical trials, approximately 1,800 per year had results information submitted to ClinicalTrials.gov and would therefore not require further submissions of results or updating of previously submitted registration information. Subtracting these 1,800 clinical trials from the 3,700 trials that were registered each year results in an estimated 1,900 clinical trials per year that would be subject to this one-time updating. We estimate that if the final rule were to go into effect 5 years after enactment of FDAAA (e.g., December 2013), there could be as many as 9,500 registered applicable clinical trials for which results have not been submitted (i.e., 1,900 clinical trials per year multiplied by 5 years), although the actual number would probably be smaller because clinical trials that had been initiated earlier would be more likely to have reached their completion date prior to the effective date of the rule and to have submitted complete clinical trial results information. We estimate that the time required to update the registration information would be, on average, 4 hours, which is half the estimated time required to submit the full set of clinical trial registration information and reflects that fact that many registration data elements would already have been submitted and would not need updating. Applying this figure to the estimated 9,500 clinical trials produces an annual hour burden of 38,000 hours. Using an average wage of $32.33 (as for the registration calculation in 1 above) and doubling it to account for benefits and overhead yields an additional cost of $2,457,080. Note that this would be a one-time cost associated with updating registration information previously submitted to ClinicalTrials.gov, not a recurring annual cost.

E. Alternatives to the Proposed Rule

Section 402(j)(3)(D)(v)(VI) of the PHS Act requires the Secretary to promulgate regulations to expand the registry and results data bank and to address specific issues that are enumerated in the statute. Section 402(j)(2)(A)(iii) of the PHS Act also authorizes the Secretary to make additions or modifications to the statutory enumerated clinical trial information required for registration. This proposed rule implements and expands the basic provisions mandated by section 402(j) of the PHS Act that became effective prior to rulemaking on the schedule established by the statute. The preamble describes various alternatives considered by the Agency in exercising its authority to add or modify the statutory provisions and in addressing the topics it was required to address via regulation. It also describes alternatives it considered in implementing statutory provisions of the law that were not required specifically to be addressed by regulation. It also invites comments on alternative approaches.

F. Regulatory Flexibility Act

The RFA (5 U.S.C. 601–612) requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This proposed rule would affect a number of small entities that conduct clinical trials of drugs and devices, but the Agency estimates that the costs incurred by small entities would be limited, especially in relation to the other costs associated with conducting a clinical trial. As explained below, the Agency believes that the final rule is not likely to have a significant economic impact on a substantial number of small entities.

The companies that would be affected by this proposed rule are classified in seven separate North American Industrial Classification System (NAICS) categories by the Census

Bureau. The affected industries are NAICS 325412—Pharmaceutical Preparation; NAICS 325414—Biological Products (except diagnostic); NAICS 334510—Electromedical and Electrotherapeutic Apparatus; NAICS 339112—Surgical and Medical Instrument; NAICS 339113—Surgical Appliance and Supplies; NAICS 339114—Dental Equipment and Supplies; NAICS 339115—Ophthalmic Goods. The Small Business Administration (SBA) size standards for all these industries define small entities as those companies with less than 500 employees, except for pharmaceutical preparation, for which it defines a small entity as one with less than 750 employees. The most recent data from the U.S. Census of Manufacturers that offers the level of detail for establishments at or near the employee size limits as defined by SBA is from 2007. In each of these establishment size categories, large majorities of the establishments meet the criteria as small entities. Even taking into account that many of these establishments are parts of multi-establishment corporations, significant numbers of companies would still qualify as small entities and have fewer than 100 employees across all of these categories. Although the Agency expects that most companies sponsoring applicable clinical trials would be larger than the average-sized company in their industry, the Agency concludes that a substantial number of companies would still qualify as small entities.

The cost analysis presented above indicates an estimated cost of compliance with this proposed rule of $6,718 per applicable clinical trial ($49,713,753 for 7,400 clinical trials per year). While some larger firms could be the responsible party for multiple applicable clinical trials in the same year, we expect most small firms would be responsible for no more than one applicable clinical trial per year. Using data from the 2007 Census of Manufacturers, the average value of shipments for establishments in these industries with one to four employees ranged from $353,000 to $844,000. Assuming that such small operations had one applicable clinical trial that was required to submit registration or results information each year, the costs of this proposed rule would represent, at most, 1.9 percent of the annual value of shipments. For establishments with 50 to 99 employees, the costs of this proposed rule would represent at most 0.6 percent of the value of shipments, even if they were responsible for 10 applicable clinical trials administered annually. For establishments with 100 or more employees, the costs of this proposed rule would represent at most 0.24 percent of the value of shipments even with 10 applicable clinical trials administered annually. These figures are well below the threshold of 3 to 5 percent of the total revenue for small entities needed to consider that this proposed rule would have a significant economic impact on a substantial number of small entities. The Agency concludes that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In practice, we expect the burden on small firms would be significantly lower than this estimate. In general the applicable clinical trials initiated by small firms would be less complex than the applicable clinical trials initiated by large firms, including, for example, fewer trial locations (sites), shorter duration, and fewer outcome measures. As a result, the amount of results information to be submitted—and the time and cost associated with such submissions—would be less than for larger entities and represent a smaller share of shipments. In addition, these costs would affect only a fraction of small firms in any given year. For example, by our estimates registration information would be required to be submitted (and results information subsequently submitted) for approximately 500 applicable device clinical trials in any given year. Information from the 2007 Census of Manufacturers indicates that there are approximately 5,600 companies in the United States that are involved in the manufacture of medical devices and that almost 4,900 of them have fewer than 100 employees. Even if no company engaged in more than one applicable clinical trial at the same time, then on average, less than 10 percent of all medical device manufacturers would initiate a trial subject to the registration and results submission requirements of this proposed rule in any given year (500 applicable device clinical trials per year divided by 5,600 firms equals 0.089 or 8.9 percent).

G. Unfunded Mandates Reform Act of 1995

Section 1352(a) of the Unfunded Mandates Reform Act of 1995 requires that the agency prepare, among other things, a written statement which includes an assessment of anticipated costs and benefits before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' 2 U.S.C. 1532(a). The current threshold, adjusted for inflation using the 2012 Implicit Price Deflator for the Gross Domestic Product, is $141 million. As indicated above, we do not expect the direct burden of this proposed rule, including the cost of compiling, submitting, and updating clinical trial registration and results information for applicable clinical trials, to result in any 1-year expenditure that would meet or exceed this amount. Nor do we expect that State or local governments would bear a significant fraction of this cost, as most of the entities affected by the proposed regulation would be private entities. As a result, we conclude that this rule will have no consequential effect on State, local, or tribal governments or on the private sector. We have determined that this proposed rule would not constitute a significant rule under the Unfunded Mandates Reform Act of 1995, because it would impose no mandates with costs exceeding the current threshold.

H. Federalism

Executive Order 13132, Federalism, establishes certain requirements that an Agency must meet when it promulgates a proposed rule (and subsequent final rule) ''that imposes substantial direct compliance costs on State and local governments,'' preempts State law, or otherwise has federalism implications. The Agency has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132 and has determined that this proposed rule does not contain policies that would impose any ''substantial direct compliance costs on State or local governments[.]'' This proposed rule, does, however, have federalism implications.

Section 801(d)(1) of FDAAA expressly provides a preemption provision as follows: ''Upon the expansion of the registry and results data bank under section 402(j)(3)(D) of the Public Health Service Act . . . no State or political subdivision of a State may establish or continue in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of Clinical trials in a database.'' We interpret this language to prohibit a State or political subdivision of a State from establishing any requirement for the inclusion of information in a database that is: (1) Clinical trial registration information, as that term is defined in § 11.10, i.e., the actual registration data elements; (2) clinical trial results information required to be submitted under section

402(j)(3) of the PHS Act and this part; or (3) information that is otherwise collected through any data element in ClinicalTrials.gov, such as information relating to voluntary submissions and other information whether or not required to be submitted under section 402(j) of the PHS Act and this part. We do not interpret section 801(d)(1) of FDAAA to preempt other types of reporting and/or data collection that States may require related to public health, disease surveillance, clinical care, or the practice of medicine such as patient and disease registries or public health surveillance registries.

Following publication of this proposed rule, the Agency will further consult with appropriate State officials and organizations to review the scope of this proposed rule and to seek input on federalism issues. We specifically solicit comments on this proposed rule from representatives of State and local governments.

VII. Paperwork Reduction Act of 1995

This proposed rule contains requirements that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA). Sections 11.28, 11.48, 11.60, 11.62, and 11.64 of this proposed rule contain information collection requirements that are subject to OMB approval. A revision of the existing PRA clearance for clinical trial registration and results submission (OMB 0925–0586) to meet the requirements of this proposed Part will be submitted to OMB for review.

A description of the information collection requirements included in this proposed rule is provided in the Regulatory Impact Statement (section V) and is summarized in this section of the preamble with an estimate of the annualized burden hours. Included in this estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing, reviewing, updating, and correcting each collection of information. The Agency invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NIH, including whether the information will have practical utility; (2) the accuracy of the estimate of the burden of the proposed collection of information by NIH, 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 information collection provisions of this proposed rule will be submitted to OMB for review. Other organizations and individuals desiring to submit comments on the information collection and submission requirements should send their comments by February 19, 2015 to (1) Ms. Seleda Perryman, Project Clearance Officer, National Institutes of Health, Rockledge Centre 1, 6705 Rockledge Drive, Room 3509, Bethesda, Maryland 20817, telephone 301–594–7949 (not a toll-free number); and (2) the Office of Information and Regulatory Affairs, OMB, *OIRA_submission@omb.eop.gov*, or by fax to 202–395–6974, and mark ''Attention: Desk Officer for the National Institutes of Health, Department of Health and Human Services.'' After we obtain OMB approval, we will publish the OMB control number in the **Federal Register**.

The estimate includes the annual hourly burden for submission, updating, and correction of information both for applicable clinical trials that are subject to this proposed rule and for the larger number of clinical trials for which information is submitted to ClinicalTrials.gov on a voluntarily basis in order to recruit subjects, remain eligible to publish summary articles in scientific journals that follow the guidelines of the ICMJE, to comply with company or other organizational policies regarding public disclosure of clinical trial information, or for other purposes.

The burden for trials that are subject to this regulation follows the estimates presented in section V of this preamble. They differ from the burden estimates contained in the current OMB Paperwork Reduction Act clearance in several ways. For registration, we have increased from 5,500 to 7,400 the estimate of the number of clinical trials that would be subject to mandatory registration under the rule. This increase reflects the revised estimate of the number of protocols for applicable clinical trials that are submitted to the FDA for under and IND or IDE. We also increased the estimated hour burden of registration from 7 hours to 8 hours to reflect the additional data elements that would be required under this proposed rule. For results submission we have increased from 1,845 to 7,400 our estimate of the number of clinical trials that would be subject to mandatory results submission under this proposed rule. This proposed rule would require the submission of results information for all registered applicable clinical trials, regardless of whether or not the drug (including biological product) or device under study in the trial is approved, licensed, or cleared. We have made commensurate increases in the estimated number of clinical trials for which a certification to delay results submission would be submitted. We have also increased the estimated hour burden for submitting results information from 25 hours to 40 hours to account for the additional results information that would be required to be submitted under this proposed rule. In addition, we have added estimates of the burden associated with the submission of registration and results information that could be triggered by some voluntary submissions of clinical trial information under proposed § 11.60. Finally, we have included a separate estimate of the burden associated with the creation of an expanded access record if a drug that is studied in an applicable clinical trial is available via an expanded access program.

TABLE 3—ESTIMATED BURDEN FOR REGISTRATION AND RESULTS SUBMISSION AT CLINICALTRIALS.GOV

Type of respondents	Number of respondents	Frequency of response	Average time per response (hours)	Annual hour burden
Regulated submissions [Subject to this proposed rule]:				
Registration	7,400	1 Initial	8	59,200
		8 Subsequent Updates	2	118,400
Results Information	7,400	1 Initial	40	296,000
		2 Subsequent Updates	10	148,000
Certifications to delay results	5,150	1	0.5	2,575

TABLE 3—ESTIMATED BURDEN FOR REGISTRATION AND RESULTS SUBMISSION AT CLINICALTRIALS.GOV—Continued

Type of respondents	Number of respondents	Frequency of response	Average time per response (hours)	Annual hour burden
Extension requests and appeals	250	1	2	500
Registration triggered by voluntary submission.	72	1	8	576
Results triggered by voluntary submission.	24	1	45	1,080
Expanded access records	78	1	2	156
SUBTOTAL				626,487
Non-regulated submissions [Not subject to this Proposed Rule]:				
Registration	9,600	1 Initial	8	76,800
		8 Subsequent Updates	2	153,600
Results Information	350	1 Initial	40	14,000
		2 Subsequent Updates	10	7,000
SUBTOTAL				251,400
TOTAL				877,887

In order to estimate the burden for clinical trials that are not subject to this proposed rule, we examined ClinicalTrials.gov to determine how many clinical trials were registered during calendar years 2008 through 2011. We found that there were, on average, some 17,000 studies registered per year, and that the number was consistent across the 3-year period. We therefore believe it is a reasonable estimate of total registrations in future years. We subtracted from this total 7,400 clinical trials to account for those applicable clinical trials that would be subject to mandatory submissions under this proposed rule. The remaining 9,600 clinical trials registered would not be subject to section 402(j) of the PHS Act, e.g., because they are studies of interventions not regulated by FDA, are phase 1 studies of drugs or feasibility studies of devices, are observational studies, or otherwise fail to meet the definition of an applicable clinical trial. This figure represents a reduction (from 11,500) in the number of non-regulated submissions to ClinicalTrials.gov that was contained in our previous OMB Paperwork Reduction Act clearance. These clinical trials would be expected to have the same clinical trial registration information submitted for them as is submitted for applicable clinical trials that are subject to this proposed rule. We expect that information submitted for such clinical trials will be updated as frequently as for clinical trials that are subject to the rule. Therefore, for calculating the registration burden associated with voluntarily submitted clinical trials, we use the same assumptions as for applicable clinical trials required to register under section 402(j)(2)(C) of the PHS Act: initial submission of registration information will take an average of 8 hours, updates of 2 hours apiece will take place 8 times during the course of the study. Applying these figures yields an estimated annual burden of 230,400 hours, of which 76,800 derives from the initial registration and 153,600 derives from updates (Table 3).

As for results submission, we do not expect that clinical trial results information will be submitted for most of the clinical trials for which registration information is submitted voluntarily (non-regulated). To estimate of the number of clinical trials for which results information would be submitted voluntarily, we reviewed the more than 7,000 results records that have been posted publicly at ClinicalTrials.gov since late 2008. Of these, about 1,050, or 350 per year, appear to be for studies that are unambiguously not applicable clinical trials, e.g., observational studies, clinical trials of interventions other than drugs (including biological products) and devices, and phase 1 clinical trials of drugs. We expect that this number of results submissions would continue to be made in future years. We estimate that the time required to submit clinical trial results information for such clinical trials would be equivalent to that for applicable clinical trials required to register under section 402(j)(2)(C) of the PHS Act. Using those figures, we estimate that the total annual hour burden for submitting clinical trial results information for voluntarily submitted clinical trials would be 14,000 hours, plus 7,000 hours for updates (Table 3). Thus the total burden associated with the voluntary submission of clinical trial information is 251,400 hours, and the total annual burden for regulated and unregulated submissions of information would be 877,887 hours.

VIII. Congressional Review Act

The U.S. Department of Health and Human Services has determined that this proposed rule is not a major rule as defined in 5 U.S.C. 804, and, thus, does not require review by Congress. The Congressional Review Act (5 U.S.C. 801–808) defines a major rule as one that the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget finds has resulted in or is likely to result in (A) an annual effect on the economy of $100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or '(C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. (5 U.S.C. 804).

As described in section V of this preamble (Regulatory Impact Statement), we estimate that the rule will impose annual costs on responsible parties (i.e., sponsors of clinical trials or designated principal investigators) of less than $50 million. We do not believe such costs are significant enough to affect prices of the drugs (including biological products) or medical devices that eventually may be approved, cleared, or licensed for marketing by

FDA. Nor do we believe that the submission and public availability of clinical trial information, as required by this proposed rule, will have significant adverse effects on competition, employment, investment, productivity, or innovation in organizations that are subject to this proposed rule. This proposed rule contains provisions to delay the public posting of information that might be considered commercially relevant, including registration information for trials of previously unapproved or uncleared devices and results information for trials of unapproved products. In addition, this proposed rule would apply to all organizations, domestic and international, that are subject to FDA regulation (i.e., because they are conducting a trial under an IND or IDE or are seeking marketing approval from FDA). Thousands of organizations have submitted information similar to the clinical trial registration information proposed in this rule to publicly available registries, including ClinicalTrials.gov, for more than a decade on a voluntary basis. Many have also made results information publicly available, though not in a consistent manner.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

IX. Legal Authority

These proposed regulations are issued under the authorities contained in 42 U.S.C. 282(i); 42 U.S.C. 282(j); 5 U.S.C. 301; 42 U.S.C. 286(a); 42 U.S.C. 241(a); 42 U.S.C. 216(b); and sections 801(c)–(d), Pub. L. 110–85, 121 Stat. 921–922 (42 U.S.C. 282(note)).

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List of Subjects in 42 CFR Part 11

Biologics, Clinical trial, Data bank, Drugs, Human subjects research, Medical devices, Medical research, Registry, Reporting and recordkeeping requirements, Results information.

For the reasons stated in this preamble, the Department of Health and Human Services proposes to amend Title 42, Chapter I of the Code of Federal Regulations by adding a Part 11 to read as follows.

PART 11—CLINICAL TRIAL REGISTRATION AND RESULTS SUBMISSION

Subpart A—General Provisions

Sec.
11.2 What is the purpose of this part?
11.4 To whom does this part apply?
11.6 What are the requirements for the submission of truthful information?
11.8 In what form and manner must clinical trial information be submitted?
11.10 What definitions apply to this part?

Subpart B—Registration

Sec.
11.20 Who must submit clinical trial registration information?
11.22 Which applicable clinical trials must be registered?
11.24 When must clinical trial registration information be submitted?
11.28 What constitutes clinical trial registration information?
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Subpart C—Results Submission

Sec.
11.40 Who must submit clinical trial results information?
11.42 For which applicable clinical trials must clinical trial results information be submitted in accordance with subpart C of this regulation?
11.44 When must clinical trial results information be submitted for applicable clinical trials subject to § 11.42?
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Subpart D—Additional Submissions of Clinical Trial Information

Sec.
11.60 What requirements apply to the voluntary submission of clinical trial information for clinical trials of FDA-regulated drugs and devices?
11.62 What requirements apply to applicable clinical trials for which submission of clinical trial information has been determined by the Director to be necessary to protect the public health?
11.64 When must clinical trial information submitted to ClinicalTrials.gov be updated?
11.66 What are the requirements for corrections of clinical trial information?

Authority: 42 U.S.C. 282(i); 42 U.S.C. 282(j); 5 U.S.C. 301; 42 U.S.C. 286(a); 42 U.S.C. 241(a); 42 U.S.C. 216(b)

Subpart A—General Provisions

§ 11.2 What is the purpose of this part?

This part implements section 402(j) of the Public Health Service Act [42 U.S.C. 282(j)] by providing requirements and procedures for the submission of clinical trial information for certain applicable clinical trials and other clinical trials to the Director of the National Institutes of Health (NIH) to be made publicly available via ClinicalTrials.gov, the Internet-accessible clinical trial registry and results data bank established by the National Library of Medicine (NLM) at *http://www.clinicaltrials.gov.*

§ 11.4 To whom does this part apply?

(a) This part applies to the responsible party for an applicable clinical trial that is required to be registered under § 11.22 or a clinical trial for which clinical trial registration information or clinical trial results information is

submitted voluntarily in accordance with § 11.60.

(b) The responsible party must communicate the identity and contact information of the responsible party to the Director by submitting the Responsible Party Contact Information data element under § 11.28(a)(4)(vii) as part of the clinical trial information submitted at the time of registration. Changes to Responsible Party Contact Information must be communicated to the Director by updating this information not later than 30 calendar days after the change has occurred, as specified in § 11.64(b)(1)(ix) and § 11.64(b)(1)(x).

(c) *Determination of responsible party.* For purposes of this part, each applicable clinical trial or other clinical trial must have one responsible party. With respect to a clinical trial, the sponsor of the clinical trial will be considered the responsible party unless and until a principal investigator has been designated the responsible party, in accordance with paragraph (c)(2) of this section. With respect to a pediatric postmarket surveillance of a device that is not a clinical trial, the responsible party is the entity whom FDA orders to conduct the pediatric postmarket surveillance of a device.

(1) *Determination of sponsor.* For purposes of this part, each applicable clinical trial or other clinical trial must have one sponsor.

(i) When an applicable clinical trial or other clinical trial is conducted under an investigational new drug application (IND) or investigational device exemption (IDE), the IND or IDE holder will be considered the sponsor.

(ii) When an applicable clinical trial or other clinical trial is not conducted under an IND or IDE, the single person or entity who initiates the trial, by preparing and/or planning the trial, and who has authority and control over the trial, will be considered the sponsor.

(2) *Designation of a principal investigator as the responsible party.* (i) The sponsor may designate a principal investigator as the responsible party if such principal investigator meets all of the following:

(A) Is responsible for conducting the trial;

(B) Has access to and control over the data from the trial;

(C) Has the right to publish the results of the trial; and

(D) Has the ability to meet all of the requirements for submitting and updating clinical trial information as specified in this part.

(ii) With regard to an applicable clinical trial or other clinical trial, a designation by the sponsor under paragraph (c)(2)(i) of this section shall consist of the sponsor providing notice of the designation to the principal investigator and obtaining from the principal investigator an acknowledgement of the principal investigator's responsibilities under this part as responsible party, and the principal investigator acknowledging the designation as responsible party to the Director in the form and manner specified at *http://prsinfo.clinicaltrials.gov.*

(3) *Withdrawal of the designation of a principal investigator as the responsible party.* (i) In the event a principal investigator who has been designated the responsible party becomes unable to meet all the requirements for being so designated under paragraph (c)(2)(i) of this section, the principal investigator must withdraw the designation in the form and manner specified at *http://prsinfo.clinicaltrials.gov,* at which time the sponsor will be considered the responsible party unless and until the sponsor makes a new designation in accordance with paragraph (c)(2) of this section.

(ii) In the event a principal investigator who has been designated the responsible party is unable because of death or incapacity to withdraw his or her designation, the sponsor will be considered the responsible party unless and until the sponsor makes a new designation in accordance with paragraph (c)(2) of this section.

§ 11.6 What are the requirements for the submission of truthful information?

(a) *General.* The clinical trial information submitted by a responsible party under this part shall not be false or misleading in any particular. Submission of false and/or misleading information would subject the responsible party to civil, criminal, and/or administrative liability under U.S. law.

(b) *Certification.* The responsible party must certify that, to the best of his or her knowledge, the information submitted is truthful and not misleading and that he or she is aware that the submission of false and/or misleading information would subject the responsible party to civil, criminal, and/or administrative liability under U.S. law.

§ 11.8 In what form and manner must clinical trial information be submitted?

Information submitted under this part must be submitted electronically to ClinicalTrials.gov, the Internet-accessible clinical trial registry and results data bank established by the National Library of Medicine, in the form and manner specified at *http://prsinfo.clinicaltrials.gov.*

§ 11.10 What definitions apply to this part?

(a) The following definitions apply to terms used in this part: *Adverse event* means any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. See also serious adverse event.

Applicable clinical trial means an applicable device clinical trial or an applicable drug clinical trial.

Applicable device clinical trial means: (1) A prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and (2) a pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act.

Applicable drug clinical trial means a controlled clinical investigation, other than a phase 1 clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of the Public Health Service Act, where ''clinical investigation'' has the meaning given in 21 CFR 312.3 (or any successor regulation) and ''phase 1'' has the meaning given in 21 CFR 312.21 (or any successor regulation). In addition, a clinical trial of a combination product, where such combination product meets the definition in 21 CFR 3.2(e), shall be considered an applicable drug clinical trial, so long as the clinical trial of the combination product is a controlled clinical investigation, other than a phase 1 clinical investigation, and the combination product is subject to section 505 of the Federal Food, Drug, and Cosmetic Act and/or section 351 of the Public Health Service Act and/or sections 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act.

Approved drug means a drug that is approved for any indication under section 505 of the Federal Food, Drug, and Cosmetic Act or a biological product licensed for any indication under section 351 of the Public Health Service Act.

Approved or cleared device means a device that is cleared for any indication under section 510(k) of the Federal Food, Drug, and Cosmetic Act or approved for any indication under sections 515 or 520(m) of that Act.

Arm means a pre-specified group or subgroup of human subjects in a clinical trial assigned to receive specific intervention(s) (or no intervention) according to a protocol.

Clinical trial means a clinical investigation or a clinical study in which human subjects are prospectively assigned, according to a protocol, to one or more interventions (or no intervention) to evaluate the effect(s) of the intervention(s) on biomedical or health related outcomes.

Clinical trial information means the data elements, including clinical trial registration information and clinical trial results information, the responsible party is required to submit to ClinicalTrials.gov under this part.

Clinical trial registration information means the data elements that the responsible party is required to submit to ClinicalTrials.gov, as listed under § 11.28.

Clinical trial results information means the data elements that the responsible party is required to submit to ClinicalTrials.gov under § 11.48 or, if applicable, § 11.60(a)(2)(i)(B).

Comparison group means a grouping of human subjects in a clinical trial that is used in analyzing the results data collected during the clinical trial.

Completion date means, for a clinical trial, the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated. In the case of clinical trials with more than one primary outcome measure with different completion dates, this term refers to the date upon which data collection is completed for all of the primary outcomes. For a pediatric postmarket surveillance of a device that is not a clinical trial, completion date means the date on which the final report summarizing the results of the pediatric postmarket surveillance is submitted to FDA.

Control or *controlled* means, with respect to a clinical trial, that data collected on human subjects in the clinical trial will be compared to concurrently collected data or to non-concurrently collected data (e.g., historical controls, including a human subject's baseline data), as reflected in the pre-specified primary or secondary outcome measures.

Device means a device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)).

Director means the NIH Director or any official of the NIH to whom the NIH Director delegates authorities granted in 42 U.S.C. 282(j).

Drug means a drug as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)) or a biological product as defined in section 351 of the Public Health Service Act (42 U.S.C. 262).

Enroll or *enrolled* means a human subject's agreement to participate in a clinical trial, as indicated by the signing of the informed consent document(s).

FDA-regulated device means, for purposes of this part, a device subject to section 510(k), 515, 520(m), or 522 of the Federal Food, Drug, and Cosmetic Act.

FDA-regulated drug means, for purposes of this part, a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or a biological product subject to section 351 of the Public Health Service Act.

Human subjects protection review board means an institutional review board (IRB) as defined in 21 CFR 50.3 or 45 CFR 46.102 (or any successor regulation), as applicable, or equivalent independent ethics committee that is responsible for ensuring the protection of the rights, safety, and well-being of human subjects involved in a clinical investigation and is adequately constituted to provide assurance of that protection.

Interventional means, with respect to a clinical study or a clinical investigation, that participants are assigned prospectively to an intervention or interventions according to a protocol to evaluate the effect of the intervention(s) on biomedical or other health related outcomes.

Investigational Device Exemption (IDE) has the meaning given in 21 CFR 812, or any successor regulation.

Investigational New Drug Application (IND) has the meaning given in 21 CFR 312.3, or any successor regulation.

NCT number means the unique identification code assigned to each record in ClinicalTrials.gov, including a record for an applicable clinical trial, a clinical trial, or an expanded access program.

Ongoing means, with respect to a clinical trial of a drug or a device and to a date, that one or more human subjects is enrolled in the clinical trial, and the date is before the completion date of the clinical trial. With respect to a pediatric postmarket surveillance of a device, ongoing means a date between the date on which FDA approves the plan for conducting the surveillance and the date on which the final report is submitted to FDA.

Outcome measure means a pre-specified measurement that will be used to determine the effect of experimental variables on the human subjects in a clinical trial. See also primary outcome measure and secondary outcome measure.

Pediatric postmarket surveillance of a device means the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information conducted under section 522 of the Federal Food, Drug, and Cosmetic Act about a marketed device that is expected to have significant use in patients who are 21 years of age or younger at the time of diagnosis or treatment. A pediatric postmarket surveillance of a device may be, but is not always, a clinical trial.

Primary outcome measure means the outcome measure(s) of greatest importance specified in the protocol, usually the one(s) used in the power calculation. Most clinical trials have one primary outcome measure, but a clinical trial may have more than one. ''Primary outcome'' has the same meaning as primary outcome measure.

Principal Investigator (PI) means the individual who is responsible for the scientific and technical direction of the study.

Protocol means the written description of the clinical trial, including objective(s), design, and methods. It may also include relevant scientific background and statistical considerations.

Responsible party means, with respect to a clinical trial, (i) the sponsor of the clinical trial, as defined in 21 CFR 50.3 (or any successor regulation); or (ii) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements under this part for the submission of clinical trial information. For a pediatric postmarket surveillance of a device that is not a clinical trial, the responsible party is the entity whom FDA orders to conduct the pediatric postmarket surveillance of the device.

Secondary outcome measure means an outcome measure that is of lesser importance than a primary outcome measure, but is part of a pre-specified plan for evaluating the effects of the intervention or interventions under

investigation in a clinical trial. A clinical trial may have more than one secondary outcome measure. ''Secondary outcome'' has the same meaning as secondary outcome measure.

Secretary means the Secretary of Health and Human Services or any other official(s) to whom the Secretary delegates the authority contained in 42 U.S.C. 282(j).

Serious adverse event means an adverse event that results in any of the following outcomes: Death, a life-threatening adverse event as defined in 21 CFR 312.32 (or any successor regulation), inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the human subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of a substance use disorder.

Sponsor means either a ''sponsor'' or ''sponsor-investigator'', as each is defined in 21 CFR 50.3, or any successor regulation.

(b) The following definitions apply to data elements of clinical trial information referenced in this part, unless otherwise specified.

(1) *Brief Title* means a short title of the clinical trial written in language intended for the lay public, including any acronym or abbreviation used publicly to identify the clinical trial.

(2) *Official Title* means the title of the clinical trial, corresponding to the title of the protocol.

(3) *Brief Summary* means a short description of the clinical trial, including a brief statement of the clinical trial's hypothesis, written in language intended for the lay public.

(4) *Primary Purpose* means the main objective of the intervention(s) being evaluated by the clinical trial.

(5) *Study Design* means a description of the manner in which the clinical trial will be conducted, including the following information:

(i) *Interventional Study Model.* The strategy for assigning interventions to human subjects.

(ii) *Number of Arms.* The number of arms in the clinical trial. For a trial with multiple periods or phases that have different numbers of arms, the maximum number of arms during any period or phase.

(iii) *Arm Information.* A description of each arm of the clinical trial that indicates its role in the clinical trial, provides an informative title, and, if necessary, additional descriptive information to differentiate each arm from other arms in the clinical trial.

(iv) *Allocation.* The method by which human subjects are assigned to arms in a clinical trial.

(v) *Masking.* The party or parties, if any, involved in the clinical trial who are prevented from having knowledge of the interventions assigned to individual human subjects.

(vi) *Single Arm Controlled.* For a single-armed clinical trial only, whether or not the clinical trial is controlled, as specified by the protocol or statistical analysis plan.

(6) *Study Phase* means, for a clinical trial of a drug, the numerical phase of such clinical trial, consistent with terminology in 21 CFR 312.21, or any successor regulation, such as phase 2 or phase 3, and in 21 CFR 312.85, or any successor regulation, for phase 4 studies.

(7) *Study Type* means the type of study for which clinical trial information is being submitted.

(8) *Whether the Study is a Pediatric Postmarket Surveillance of a Device* means, for a study that includes a device as an intervention and is a pediatric postmarket surveillance of a device, an affirmation that the study is a pediatric postmarket surveillance of a device.

(9) *Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study* means the name(s) of the disease(s) or condition(s) studied in the clinical trial, or the focus of the clinical trial, using, if available, appropriate descriptors from the National Library of Medicine's Medical Subject Headings (MeSH) controlled vocabulary thesaurus *http://www.nlm.nih.gov/mesh/,* or terms from another vocabulary, such as the Systematized Nomenclature of Medicine—Clinical Terms (SNOMED CT), that has been mapped to MeSH within the Unified Medical Language System (UMLS) Metathesaurus, *https://uts.nlm.nih.gov.*

(10) *Intervention Name* means a brief descriptive name used to refer to the intervention(s) studied in each arm of the clinical trial. A non-proprietary name of the intervention must be used, if available. If a non-proprietary name is not available, a brief descriptive name or identifier must be used.

(11) *Other Intervention Name(s)* means other current and former name(s) or alias(es), if any, different from the Intervention Name(s), that the sponsor has used publicly to identify the intervention(s), including, but not limited to, past or present names such as brand name(s), serial numbers, or chemical descriptions.

(12) *Intervention Description* means, details that can be made public about the intervention, other than the Intervention Name and Other Intervention Name(s), sufficient to distinguish it from other, similar interventions studied in the same or another clinical trial.

(13) *Intervention Type* means, for each intervention studied in the clinical trial, the general type of intervention.

(14) *U.S. FDA Approval, Licensure, or Clearance Status* means, for each drug or device studied in the clinical trial, whether that drug or device is approved, licensed, or cleared by the U.S. Food and Drug Administration for any use.

(15) *Product Manufactured in the U.S.* means, for a drug or device studied in a clinical trial, whether or not the drug or device is manufactured in the U.S. or one of its territories.

(16) *Study Start Date* means the estimated date on which the clinical trial will be open to enrollment of human subjects. If the clinical trial has enrolled the first human subject, the actual date on which the first human subject was enrolled.

(17) *Completion Date* means the estimated completion date. Once the clinical trial has reached the completion date, the responsible party must update the Completion Date data element to reflect the actual completion date.

(18) *Enrollment* means the estimated total number of human subjects to be enrolled or target number of human subjects in the clinical trial.

(19) *Primary Outcome Measure Information* means a description of each primary outcome measure, to include the following information:

(i) Name of the specific primary outcome measure;

(ii) Description of the metric used to characterize the specific primary outcome measure; and

(iii) Time point(s) at which the measurement is assessed for the specific metric used.

(20) *Secondary Outcome Measure Information* means a description of each secondary outcome measure, to include the following information:

(i) Name of the specific secondary outcome measure;

(ii) Description of the metric used to characterize the specific secondary outcome measure; and

(iii) Time point(s) at which the measurement is assessed for the specific metric used.

(21) *Eligibility Criteria* means a limited list of criteria for selection of human subjects to participate in the clinical trial, provided in terms of inclusion and exclusion criteria and suitable for assisting potential human subjects in identifying clinical trials of interest.

(22) *Gender* means the biological sex of the human subjects who may participate in the clinical trial.

(23) *Age Limits* means the minimum and maximum age of human subjects who may participate in the clinical trial, provided in relevant units of time.

(24) *Accepts Healthy Volunteers* means whether human subjects who do not have a disease or condition, or related conditions or symptoms, under study in the clinical trial are permitted to participate in the clinical trial.

(25) *Overall Recruitment Status* means the recruitment status for the clinical trial as a whole, based upon the status of the individual sites. If at least one facility in a multi-site clinical trial has an individual site status of ''recruiting,'' then the overall recruitment status for the trial must be ''recruiting.''

(26) *Why Study Stopped* means, for a clinical trial that is suspended or terminated or withdrawn prior to its completion as anticipated by the protocol, a brief explanation of the reason(s) why such clinical trial was stopped.

(27) *Actual Enrollment* means, for a clinical trial for which recruitment of human subjects has terminated or completed, the actual number of human subjects enrolled in the clinical trial.

(28) *Individual Site Status* means the recruitment status of each participating facility in a clinical trial.

(29) *Availability of Expanded Access* means, for an applicable drug clinical trial of a drug that is not an approved drug:

(i) An indication of whether there is expanded access to the drug under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) for those who do not qualify for enrollment in the applicable clinical trial.

(ii) If expanded access is available under section 561 of the Federal Food, Drug, and Cosmetic Act, the NCT number of the expanded access record.

(30) *Name of the Sponsor* means the name of the entity or the individual that is the sponsor of the clinical trial, as defined in § 11.10(a).

(31) *Responsible Party, by Official Title* means:

(i) Indication of whether the responsible party is the sponsor of the clinical trial, as that term is defined in 21 CFR 50.3, the sponsor-investigator, as that term is defined in 21 CFR 50.3, or a principal investigator designated pursuant to this part; and

(ii) Either:

(A) The official name of the entity, if the responsible party is an entity; or

(B) The official title and primary organizational affiliation of the individual, if the responsible party is an individual.

(32) *Facility Information* means, for each participating facility in a clinical trial, the following information:

(i) Facility Name, meaning the full name of the organization where the clinical trial is being conducted;

(ii) Facility Location, including city, state, country and zip code for U.S. locations (including territories of the United States) and city and country for locations in other countries; and

(iii) Either:

(A) For each facility participating in a clinical trial, Facility Contact, including the name or title, telephone number, and email address of a person to whom questions concerning the trial and enrollment at that site can be addressed; or

(B) Central Contact Person, including the name or title, toll-free telephone number and email address of a person to whom questions concerning enrollment at any location of the trial can be addressed.

(33) *Unique Protocol Identification Number* means any unique identification number assigned to the protocol by the sponsor.

(34) *Secondary ID* means:

(i) Any identification number(s) other than the organization's unique protocol identification number or NCT number that is assigned to the clinical trial, including any unique clinical trial identification numbers assigned by other publicly available clinical trial registries. If the clinical trial is funded in whole or part by a U.S. federal government agency, the complete grant or contract number must be submitted as a Secondary ID.

(ii) A description of the type of Secondary ID.

(35) *Food and Drug Administration IND or IDE Number* means whether or not there is an IND or IDE for the clinical trial and, if so, each of the following elements:

(i) Name or abbreviation of the FDA center with whom the IND or IDE is filed;

(ii) IND or IDE number assigned by the FDA center; and

(iii) For an IND, the IND serial number (as defined in 21 CFR 312.23(e), or any successor regulation), if any, assigned to the clinical trial.

(36) *Human Subjects Protection Review Board Status* means information to indicate whether a clinical trial has been approved by a human subjects protection review board or is exempt from human subjects protection review board approval. Human Subjects Protection Review Board Status must be listed as ''approved'' if at least one human subjects protection review board has approved the clinical trial;

(37) *Record Verification Date* means the date upon which the responsible party last verified the clinical trial information in the entire ClinicalTrials.gov record for the clinical trial, even if no additional or updated information was submitted at that time.

(38) *Responsible Party Contact Information* means administrative information to identify and allow communication with the responsible party by telephone, email, and regular mail or delivery service. Responsible Party Contact Information includes the name, official title, organizational affiliation, physical address, mailing address, phone number, and email address of the individual who is the responsible party or of a designated employee of the organization that is the responsible party.

(39) *Studies an FDA-regulated Device* means a clinical trial studies a device subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act.

(40) *Studies an FDA-regulated Drug* means a clinical trial studies a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of the Public Health Services Act

Subpart B—Registration

§ 11.20 Who must submit clinical trial registration information?

The responsible party for an applicable clinical trial specified in § 11.22 must register the applicable clinical trial by submitting clinical trial registration information specified in § 11.28 for that clinical trial.

§ 11.22 Which applicable clinical trials must be registered?

(a) *General specification.* (1) Any applicable clinical trial that is initiated after September 27, 2007, must be registered.

(2) Any applicable clinical trial that is initiated on or before September 27, 2007, and is ongoing on December 26, 2007, must be registered.

(3) Determining the date of initiation for an applicable clinical trial. An applicable clinical trial, other than a pediatric postmarket surveillance of a device that is not a clinical trial, is considered to be initiated on the date on which the first human subject is enrolled. A pediatric postmarket surveillance of a device that is not a clinical trial is considered to be initiated on the date on which U.S. Food and Drug Administration (FDA) approves the plan for conducting the surveillance.

(b) *Determination of applicable clinical trial.* For purposes of this part, any clinical trial or study that, at any point in time, is described accurately by the data elements listed in paragraph (b)(1) or (2) of this section will be considered to meet the definition of an applicable clinical trial.

(1) *Applicable device clinical trial.* A clinical trial or study that is described accurately by the data elements listed in either paragraph (b)(1)(i) or (ii) of this section meets the definition of an applicable device clinical trial:

(i) The study is a pediatric postmarket surveillance of a device as required by FDA under section 522 of the Federal Food, Drug, and Cosmetic Act.

(ii) The study is a clinical trial that meets all of the following criteria:

(A) Study Type is interventional;

(B) Primary Purpose of the clinical trial is other than a feasibility study;

(C) Either:

(*1*) Number of Arms is two or more; or

(*2*) Number of Arms is one, and the clinical trial is Single Arm Controlled;

(D) The Intervention Type is other than a combination product;

(E) The clinical trial Studies an FDA-regulated Device; and

(F) One or more of the following applies:

(*1*) At least one Facility Location is within the U.S. or one of its *territories,*

(*2*) A device under investigation is a Product Manufactured in the U.S. or one of its territories and exported for study in another country, or

(*3*) The clinical trial has a U.S. Food and Drug Administration IDE Number.

(2) *Applicable drug clinical trial.* A clinical trial that is described accurately by the following data elements meets the definition of an applicable drug clinical trial:

(i) Study Type is interventional;

(ii) Study Phase is other than phase 1;

(iii) Either:

(A) Number of Arms is two or more, or

(B) Number of Arms is one, and the clinical trial is Single Arm Controlled;

(iv) The clinical trial Studies an FDA-regulated Drug; and

(v) One or more of the following applies:

(A) At least one Facility Location for the clinical trial is within the U.S. or one of its territories,

(B) A drug under investigation is a Product Manufactured in the U.S. or one of its territories and exported for study in another country, or

(C) The clinical trial has a U.S. Food and Drug Administration IND Number.

§ 11.24 When must clinical trial registration information be submitted?

(a) *General.* Except as provided in paragraph (b) of this section, the responsible party for an applicable clinical trial subject to § 11.22 must submit clinical trial registration information, as specified in § 11.28(a), not later than December 26, 2007, or 21 calendar days after the first human subject is enrolled, whichever date is later.

(b) *Exceptions.* (1) The responsible party for an applicable clinical trial subject to § 11.22 that is not for a serious or life-threatening disease or condition must submit clinical trial registration information not later than September 27, 2008, or 21 calendar days after the first human subject is enrolled, whichever date is later.

(2) The responsible party for an applicable device clinical trial that is a pediatric postmarket surveillance of a device and is not a clinical trial must submit clinical trial registration information, as specified in § 11.28(b), not later than December 26, 2007, or 21 calendar days after the U.S. Food and Drug Administration approves the postmarket surveillance plan, whichever date is later.

§ 11.28 What constitutes clinical trial registration information?

(a) For each applicable clinical trial that must be registered with ClinicalTrials.gov as required by § 11.22, other than a pediatric postmarket surveillance of a device that is not a clinical trial, the responsible party must provide the data elements listed below in (1) through (4), as they are defined in § 11.10(b):

(1) Descriptive information:

(i) Brief Title;

(ii) Official Title;

(iii) Brief Summary;

(iv) Primary Purpose;

(v) Study Design;

(vi) Study Phase, for an applicable drug clinical trial;

(vii) Study Type;

(viii) Whether the Study is a Pediatric Postmarket Surveillance of a Device; for an applicable device clinical trial that is a Pediatric Postmarket Surveillance of a Device;

(ix) Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study;

(x) Intervention Name, for each intervention studied;

(xi) Other Intervention Name(s), for each intervention studied;

(xii) Intervention Description, for each intervention studied;

(xiii) Intervention Type, for each intervention studied;

(xiv) Studies an FDA-Regulated Device;

(xv) Studies an FDA-Regulated Drug;

(xvi) U.S. FDA Approval, Licensure, or Clearance Status, for each intervention studied;

(xvii) Product Manufactured in the U.S., for each intervention studied, if the entry for U.S. Food and Drug Administration IND or IDE number in § 11.28(a)(4)(iii) indicates that there is no IND or IDE for the clinical trial, and the entry(ies) for Facility Information in § 11.28(a)(3)(iii) include no facility locations in the United States or its territories.

(xviii) Study Start Date;

(xiv) Completion Date.

(xx) Enrollment;

(xxi) Primary Outcome Measure Information, for each primary outcome measure.

(xxii) Secondary Outcome Measure Information, for each secondary outcome measure.

(2) Recruitment information:

(i) Eligibility Criteria;

(ii) Gender;

(iii) Age Limits;

(iv) Accepts Healthy Volunteers;

(v) Overall Recruitment Status.

(vi) Why Study Stopped?

(vii) Actual Enrollment.

(viii) Individual Site Status;

(ix) Availability of Expanded Access, for an applicable drug clinical trial of a drug that is not an approved drug. If expanded access is available under section 561 of the Federal Food, Drug, and Cosmetic Act, and the expanded access record for the drug has not been submitted in accordance with § 11.28(c), the data elements listed § 11.28(c) must also be submitted.

(3) Location and contact information:

(i) Name of the Sponsor;

(ii) Responsible Party, by Official Title;

(iii) Facility information.

(4) Administrative data:

(i) Unique Protocol Identification Number.

(ii) Secondary IDs.

(iii) Food and Drug Administration IND or IDE number.

(iv) Human Subjects Protection Review Board Status.

(v) Record Verification Date.

(vii) Responsible Party Contact Information.

(b) Pediatric postmarket surveillance of a device that is not a clinical trial. For each pediatric postmarket surveillance of a device that is not a clinical trial, that must be registered with ClinicalTrials.gov as required by § 11.22, the responsible party must provide the information listed below in paragraphs (b)(1) through (3) of this section.

(1) Descriptive information:

(i) *Brief Title.* A short title of the pediatric postmarket surveillance of a device in language intended for the lay public. If an acronym or abbreviation is used to publicly identify the surveillance, it must be provided.

(ii) *Official Title.* The title of the pediatric postmarket surveillance of a device, corresponding to the title of the protocol or the FDA-approved plan for conducting the surveillance.

(iii) *Brief Summary.* A short description of the pediatric postmarket surveillance of a device, including a brief statement of the hypothesis or objective, written in language intended for the lay public, and a general description of the surveillance design including relevant population information.

(iv) *Study Type.* The type of study being registered. In the case of a pediatric postmarket surveillance of a device that is not a clinical trial, a study type of ''observational'' is required.

(v) *Whether the Study is a Pediatric Postmarket Surveillance of a Device.* For a study that includes a device as an intervention and is a pediatric postmarket surveillance of a device, an affirmation that the study is a pediatric postmarket surveillance of a device.

(vi) *Primary Disease or Condition Being Studied, or the Focus of the Study.* The name(s) of the disease(s) or condition(s) being studied in the pediatric postmarket surveillance of a device, or the focus of the study, using, if available, appropriate descriptors from the National Library of Medicine's Medical Subject Headings (MeSH) controlled vocabulary thesaurus, *http://www.nlm.nih.gov/mesh/,* or terms from another vocabulary, such as the Systematized Nomenclature of Medicine—Clinical Terms (SNOMED CT), that has been mapped to MeSH within the Unified Medical Language System (UMLS) Metathesaurus, *https://uts.nlm.nih.gov.*

(vii) *Intervention Name(s).* A brief descriptive name used to refer to each intervention studied in the pediatric postmarket surveillance of a device. A non-proprietary name of the intervention must be used, if available. If a non-proprietary name is not available, a brief descriptive name or identifier must be used.

(viii) *Other Intervention Name(s).* Any other current and former name(s) or alias(es), different from the Intervention Name(s), that the sponsor has used publicly to identify the intervention(s), including, but not limited to, past or present names such as brand name(s), serial numbers, or chemical descriptions.

(ix) *Intervention Description.* Details that can be made public about each intervention, other than the Intervention Name and Other Intervention Name, sufficient to distinguish it from other, similar interventions studied in the same or another clinical trial or pediatric postmarket surveillance of a device that is not a clinical trial.

(x) *Intervention Type.* For each intervention studied in the pediatric postmarket surveillance of a device, the general type of intervention.

(xi) *Study Start Date.* The date on which FDA approves the pediatric postmarket surveillance plan, as specified in 21 CFR 822.19(a) (or any successor regulation).

(xii) *Completion Date.* The estimated date on which the final report summarizing the results of the pediatric postmarket surveillance of a device is expected to be submitted to FDA. Once the final report has been submitted, the actual date on which the final report is submitted to FDA.

(2) Location and contact information:

(i) Name of the Sponsor.

(ii) Responsible Party, by Official Title.

(A) If the responsible party is an entity, the official name of the entity; or

(B) If the responsible party is an individual, the official title and primary organizational affiliation of the individual.

(iii) *Contact Information.* The name or official title, toll-free telephone number and email address of a person to whom questions concerning the pediatric postmarket surveillance of a device can be addressed.

(3) Administrative data:

(i) *Unique Protocol Identification Number.* The unique identification number assigned to the pediatric postmarket surveillance of a device by the sponsor, if any.

(ii) *Secondary IDs.* (A) Identification number(s) other than the organization's unique protocol identification number or NCT number that is assigned to the pediatric postmarket surveillance of a device, if any, including any unique identification numbers assigned by other publicly available registries. If the pediatric postmarket surveillance of a device is funded in whole or part by a U.S. Federal Government agency, the complete grant or contract number must be submitted as a Secondary ID.

(B) For each secondary ID listed, a description of the type of secondary ID.

(iii) *Human Subjects Protection Review Board Status.* Information to indicate whether a pediatric postmarket surveillance of a device has been approved by a human subjects protection review board or is exempt from (or otherwise not required to receive) human subjects protection review board approval. Human Subjects Protection Review Board Status must be listed as ''approved'' if at least one human subjects protection review board has approved the pediatric postmarket surveillance.

(iv) *Record Verification Date.* The date upon which the responsible party last verified the clinical trial information in the entire ClinicalTrials.gov record for the pediatric postmarket surveillance of a device, even if no additional or updated information was submitted at that time.

(v) *Responsible Party Contact Information.* Administrative information sufficient to identify and allow communication with the responsible party by telephone, email, and regular mail or delivery service. Responsible Party Contact Information includes the name, official title, organizational affiliation, physical address, mailing address, phone number, and email address of the individual who is the responsible party or of a designated employee of the organization that is the responsible party.

(c) *Expanded access record.* If expanded access is available under section 561 of the Federal Food, Drug, and Cosmetic Act to a drug studied in an applicable drug clinical trial and the data elements set forth in paragraphs (b)(1) through (4) of this section have not been submitted via an expanded access record for a previously-registered applicable clinical trial of that drug, the responsible party must submit the clinical trial information specified in paragraphs (b)(1) through (4) of this section to ClinicalTrials.gov in the form of an expanded access record. If a responsible party voluntarily submits an expanded access record for a device, then the responsible party must submit the clinical trial information specified in paragraphs (b)(1) through (4) of this section.

(1) Descriptive information:

(i) *Brief Title.* A short title of the expanded access program written in language intended for the lay public. If an acronym or abbreviation is used

publicly to identify the program, it must be provided.

(ii) *Official Title.* The title of the expanded access program, corresponding to the title of the program permitted by FDA.

(iii) *Brief Summary.* A short description of the expanded access program, including the procedure for requesting the treatment.

(iv) *Study Type.* The type of study that is being registered, in this case an ''expanded access program.''

(v) *Primary Disease or Condition.* The name(s) of the disease(s) or condition(s) for which expanded access to the drug is offered, using, if available, appropriate descriptors from the National Library of Medicine's Medical Subject Headings (MeSH) controlled vocabulary thesaurus *http://www.nlm.nih.gov/mesh/,* or terms from another vocabulary, such as the Systematized Nomenclature of Medicine—Clinical Terms (SNOMED CT), that has been mapped to MeSH within the Unified Medical Language System (UMLS) Metathesaurus, *https://uts.nlm.nih.gov.*

(vi) *Intervention Name(s).* A brief descriptive name used to refer to the drug that is available through the expanded access program. A non-proprietary name of the intervention must be used, if available. If a non-proprietary name is not available, a brief descriptive name or identifier must be used.

(vii) *Other Intervention Name(s).* Any other current and former name(s) or alias(es), different from the Intervention Name(s), that the sponsor has used publicly to identify the intervention, including, but not limited to, past or present names such as brand name(s), serial numbers, or chemical descriptions.

(viii) *Intervention Description.* Details that can be made public about each intervention, other than the Intervention Name or Other Intervention Name, sufficient to distinguish it from other, similar interventions available through other expanded access programs or clinical trials.

(ix) *Intervention Type.* For each intervention available through the expanded access program, the general type of intervention.

(2) Recruitment information:

(i) *Eligibility Criteria.* A limited list of criteria for determining who is eligible to receive treatment in the expanded access program, provided in terms of inclusion and exclusion criteria and suitable for assisting potential patients in identifying expanded access programs of interest.

(ii) *Gender.* The biological sex of the patients who may receive treatment in the expanded access program.

(iii) *Age Limits.* The minimum and maximum age of patients who may receive treatment in the expanded access program, provided in relevant units of time.

(iv) *Expanded Access Status.* The status of availability of the investigational drug through the expanded access program.

(3) Location and Contact Information:

(i) Name of the Sponsor.

(ii) Responsible Party, by Official Title.

(A) If the responsible party entering the clinical trial information into the expanded access record is an entity, the official name of the entity; or

(B) If the responsible party entering the clinical trial information into the expanded access record is an individual, the official title and primary organizational affiliation of the individual.

(iii) *Contact Information.* The name or official title, toll-free telephone number, and email address of a person to whom questions concerning the expanded access program can be addressed.

(4) *Administrative data.* (i) Unique Protocol Identification Number. Any unique identification number assigned to the expanded access program by the sponsor.

(ii) *Secondary IDs.*(A) Any identification number(s) other than the organization's unique protocol identification number or the NCT number that is assigned to the expanded access program, including any unique identification numbers assigned by other publicly available clinical trial or expanded access registries.

(B) For each Secondary ID listed, a description of the type of Secondary ID.

(iii) *Food and Drug Administration IND Number.* The IND number for the expanded access program, which must include each of the following elements:

(A) Name or abbreviation of the FDA center with whom the IND is filed (i.e., CDER, CBER);

(B) IND number assigned by the FDA center; and

(C) IND serial number (as defined in 21 CFR 312.23(e), or any successor regulation), if any, assigned to the expanded access program.

(iv) *Record Verification Date.* The date upon which the responsible party last verified the clinical trial information in the entire ClinicalTrials.gov record for the expanded access program, even if no additional or updated information was submitted at that time.

(v) *Responsible Party Contact Information.* Administrative information sufficient to identify and allow communication with the responsible party entering the clinical trial information into the expanded access record by telephone, email, and regular mail or delivery service. Responsible Party Contact Information includes the name, official title, organizational affiliation, physical address, mailing address, phone number, and -email address of the individual who is the responsible party or of a designated employee of the organization that is the responsible party.

§ 11.35 By when will NIH post clinical trial registration information submitted under § 11.28?

(a) *Applicable drug clinical trial.* NIH will post publicly at ClinicalTrials.gov the clinical trial registration information, except for certain administrative data, for an applicable drug clinical trial not later than 30 calendar days after the responsible party has submitted such information in accordance with § 11.24 of this part.

(b) *Applicable device clinical trial.* (1) For an applicable device clinical trial of a device that previously was approved or cleared, NIH will post publicly at ClinicalTrials.gov the clinical trial registration information, except for certain administrative data, not later than 30 calendar days after clinical trial results information is required to be posted in accordance with § 11.52 of this part.

(2) For an applicable device clinical trial of a device that has not been previously approved or cleared, NIH will post publicly at ClinicalTrials.gov the clinical trial registration information, except for certain administrative data, not earlier than the date of FDA approval or clearance of the device, and not later than 30 calendar days after the date of such approval or clearance.

Subpart C—Results Submission

§ 11.40 Who must submit clinical trial results information?

The responsible party for an applicable clinical trial specified in § 11.42 must submit clinical trial results information for that clinical trial.

§ 11.42 For which applicable clinical trials must clinical trial results information be submitted in accordance with subpart C of this regulation?

Unless a waiver of the requirement to submit clinical trial results information is granted in accordance with § 11.54, clinical trial results information must be submitted for any applicable clinical trial for which submission of clinical

trial registration information is required under § 11.22 and that meets one of the following criteria:

(a) The completion date of the clinical trial is on or after the effective date of this rule; or

(b) The completion date of the clinical trial is prior to the effective date of this rule, the applicable deadline established by § 11.44 is on or after the effective date of the rule, and clinical trial results information is submitted on or after the effective date of the rule, consistent with the applicable deadline established by § 11.44.

§ 11.44 When must clinical trial results information be submitted for applicable clinical trials subject to § 11.42?

(a) *Standard submission deadlines* (1) In general, clinical trial results information specified in § 11.48 must be submitted no later than 1 year after the completion date, except as otherwise provided in this section.

(2) Submitting clinical trial results information following initial approval, licensure, or clearance. Except as otherwise provided in §§ 11.44(b), (c), (d) or (e), for any applicable clinical trial of an FDA-regulated drug or device that is not approved, licensed, or cleared as of the completion date and that receives initial FDA approval, licensure, or clearance thereafter, clinical trial results information specified in § 11.48(a) must be submitted by the earlier of the following:

(i) The submission deadline specified in § 11.44(a)(1); or

(ii) The date that is 30 calendar days after FDA approves, licenses, or clears the drug or device for any indication studied in the applicable clinical trial.

(b) *Delayed submission of results with certification if seeking approval, licensure, or clearance of a new use.* (1) If, prior to the results submission deadline specified under paragraph (a)(1) of this section, the responsible party submits to ClinicalTrials.gov a certification that an applicable clinical trial involves an FDA-regulated drug or device that previously has been approved, licensed, or cleared, for which the manufacturer is the sponsor of the applicable clinical trial, and for which an application or premarket notification seeking approval, licensure, or clearance of the use being studied (which is not included in the labeling of the approved, licensed, or cleared drug or device) has been filed or will be filed within 1 year with FDA, the deadline for submitting complete clinical trial results information will be 30 calendar days after the earliest of the following events:

(i) FDA approves, licenses, or clears the drug or device for the use studied in the applicable clinical trial;

(ii) FDA issues a letter that ends the regulatory review cycle for the application or submission but does not approve, license, or clear the drug or device for the use studied in the applicable clinical trial; or

(iii) The application or premarket notification seeking approval, licensure, or clearance of the new use is withdrawn without resubmission for not less than 210 calendar days.

(2) *Two-year limitation.* Notwithstanding the deadlines specified in paragraph (b)(1) of this section, the responsible party must submit complete clinical trial results information not later than the date that is 2 years after the date that the certification was submitted, except to the extent that paragraph (d) of this section applies.

(3) *Additional Requirements.* If a responsible party who is both the manufacturer of the drug or device studied in an applicable clinical trial and the sponsor of the applicable clinical trial submits a certification in accordance with paragraph (b)(1) of this section, that responsible party must submit such a certification for each applicable clinical trial that meets the following criteria:

(i) The applicable clinical trial is required to be submitted in an application or premarket notification for seeking approval, licensure, or clearance of a new use; and

(ii) The applicable clinical trial studies the same drug or device for the same use as studied in the applicable clinical trial for which the initial certification was submitted.

(c) *Delayed submission of results with certification if seeking initial approval, licensure or clearance of a drug or device.* (1) If, prior to the submission deadline specified under paragraph (a)(1) of this section, a responsible party submits to ClinicalTrials.gov a certification that an applicable clinical trial studies an FDA-regulated drug or device that was not approved, licensed, or cleared by FDA for any use before the completion date of the trial, and that the sponsor intends to continue with product development and is either seeking, or may at a future date seek FDA approval, licensure, or clearance of the drug or device under study, the deadline for submitting complete clinical trial results information will be 30 calendar days after the earlier of the date on which:

(i) FDA approves, licenses, or clears the drug or device for any indication that is studied in the applicable clinical trial;

(ii) The marketing application or premarket notification is withdrawn without resubmission for not less than 210 calendar days.

(2) *Two-year limitation.* Notwithstanding the deadlines established in paragraph (c)(1) of this section, the responsible party must submit complete clinical trial results information not later than 2 years after the date on which the certification was submitted, except to the extent that paragraph (d) of this section applies.

(d) *Submitting partial results.* (1) If required clinical trial results information specified in § 11.48 has not been collected for a secondary outcome measure by the completion date, the responsible party must submit clinical trial results information for that secondary outcome measure by the later of:

(i) 1 year after the date on which the final subject is examined or receives an intervention for the purposes of final collection of data for that secondary outcome measure, whether the clinical trial was concluded according to the pre-specified protocol or was terminated, or

(ii) If a certification to delay results submission has been submitted under paragraph (b) or (c) of this section, the date on which results information for the primary outcome measures are due pursuant to paragraph (b) or (c) of this section.

(2) If clinical trial results information was submitted for the primary outcome measure(s) prior to the effective date of the rule but data collection for all of the secondary outcome measure(s) is not completed until on or after the effective date of the rule, clinical trial results information for all primary and secondary outcome measures must be submitted in accordance with § 11.48 not later than 1 year after the date on which the final subject is examined or receives an intervention for the purposes of final collection of data for such secondary outcome measure(s), whether the clinical trial was concluded according to the pre-specified protocol or was terminated.

(e) *Extensions.* (1) Requesting a good-cause extension of the results submission deadline. A responsible party may request a good-cause extension of the deadline for submitting clinical trial results information to ClinicalTrials.gov subject to paragraphs (e)(1)(i) and (ii) of this section. A responsible party may request more than one good-cause extension for the same applicable clinical trial and may request a good-cause extension of a delayed results submission deadline established by the submission of a

certification as described in paragraph (b) or (c) of this section.

(i) The responsible party must submit a request for a good-cause extension to ClinicalTrials.gov prior to the date on which clinical trial results information would otherwise be due in accordance with paragraph (a), (b), (c), (d), or (f) of this section.

(ii) A request for a good-cause extension must contain the following elements:

(A) Description of the reason(s) why clinical trial results information cannot be provided according to the deadline, with sufficient detail to allow evaluation of the request; and

(B) Estimate of the date on which the clinical trial results information will be submitted.

(2) *Decision and submission deadline.* The NIH will provide a written response electronically to the responsible party indicating whether or not the requested extension has been granted, and the responsible party must either submit clinical trial results information not later than the deadline established by paragraphs (e)(2)(i) or (ii) of this section, as applicable, or appeal the denial in accordance with paragraph (e)(3) of this section.

(i) If the good-cause extension request is granted, the responsible party must submit clinical trial results information not later than the date of the deadline specified in the electronic response.

(ii) If the good-cause extension request is denied, the responsible party must either appeal in accordance with paragraph (e)(3) of this section or submit complete clinical trial results information by the later of the original submission deadline specified in paragraph (a), (b), (c), (d), or (f) of this section, as applicable, or 15 calendar days after the date on which the electronic notice of the denial is sent to the responsible party.

(3) *Appealing a denied extension request.* (i) A responsible party who seeks to appeal a denied extension request or the deadline specified in a granted extension must submit an appeal in the form of a written letter to the Director not later than 15 calendar days after the date on which the electronic notification of grant or denial of the request is sent to the responsible party.

(ii) An appeal letter must contain an explanation of the reason(s) why the initial decision to deny an extension request or to grant an extension request with a shorter deadline than requested should be overturned or revised.

(iii) The Director will provide an electronic notification to the responsible party indicating whether or not the requested extension has been granted upon appeal.

(iv) If the Director grants the extension request upon appeal, the responsible party must submit clinical trial results information not later than the deadline specified in the electronic notification specified in paragraph (e)(3)(iii) of this section.

(v) If the Director denies an appeal of a denied extension request, the responsible party must submit clinical trial results information by the later of the original submission deadline specified in paragraph (a), (b), (c), (d) or (f) of this section, or 15 calendar days after the electronic notification of the denial upon appeal specified in paragraph (e)(3)(iii) of this section, is sent to the responsible party.

(vi) If the Director denies an appeal of a deadline specified in a granted extension request, the responsible party must submit clinical trial results information by the later of the deadline specified in the notification granting the extension request, specified in paragraph (e)(2)(i) of this section or 15 calendar days after the electronic notification denying the appeal, specified in paragraph (e)(3)(iii) of this section, is sent to the responsible party.

(f) Pediatric postmarket surveillance of a device that is not a clinical trial. For each pediatric postmarket surveillance of a device that is not a clinical trial as defined in this part, the responsible party must submit clinical trial results information as specified in § 11.48(b) not later than 30 calendar days after the date on which the final report of the approved pediatric postmarket surveillance of a device as specified in 21 CFR 822.38 (or any successor regulation) is submitted to FDA.

§ 11.48 What constitutes clinical trial results information?

(a) For each applicable clinical trial other than a pediatric postmarket surveillance of a device that is not a clinical trial for which clinical trial results information must be submitted under § 11.42, the responsible party must provide the following:

(1) *Participant flow.* Information for completing a table documenting the progress of human subjects through a clinical trial by arm, including the number who started and completed the clinical trial. This information must include the following elements:

(i) Participant Flow Arm Information. A brief description of each arm used for describing the flow of human subjects through the clinical trial, including a descriptive title used to identify each arm.

(ii) Pre-assignment Information. A description of significant events affecting the number of human subjects enrolled in the clinical trial but not assigned to an arm, if any.

(iii) Participant Data. The number of human subjects that started and completed the clinical trial, by arm.

(2) *Demographic and baseline characteristics.* Information for completing a table of demographic and baseline measures and data collected by arm or comparison group and for the entire population of human subjects who participated in the clinical trial. This information must include the following elements:

(i) *Baseline Characteristics Arm/Group Information.* A brief description of each arm or comparison group used for describing the demographic and baseline characteristics of the human subjects in the clinical trial, including a descriptive title used to identify each arm or comparison group.

(ii) *Overall Number of Baseline Participants.* The total number of human subjects for whom baseline characteristics were measured, by arm or comparison group, and overall.

(iii) *Baseline Measure Information.* A description of each baseline or demographic characteristic measured in the clinical trial, including age, gender, and any other measure(s) that were assessed at baseline and are used in the analysis of outcome measures in accordance with § 11.48(a)(3). The description of each measure must include the following elements:

(A) Name and Description of the measure, including any categories that are used in submitting the results;

(B) *Measure Type and Measure of Dispersion:* For each baseline measure submitted, an indication of the type of data to be submitted and, the associated measure of dispersion;

(C) *Unit of measure.*

(iv) *Baseline Measure Data.* The value(s) for each submitted baseline measure, by arm or comparison group and for the entire population of human subjects who participated in the clinical trial.

(3) *Outcomes and statistical analyses.* Information for completing a table of data for each primary and secondary outcome measure by arm or comparison group, including the result(s) of scientifically appropriate statistical analyses that were performed on the outcome measure data, if any. This information must include the following elements:

(i) *Outcome Measure Arm/Group Information.* A brief description of each arm or comparison group used for submitting an outcome measure for the

clinical trial, including a descriptive title to identify each arm or comparison group.

(ii) *Analysis Population Information* (A) Number of Participants Analyzed. The number of human subjects for which an outcome was measured and analyzed, by arm or comparison group.

(B) Number of Units Analyzed. If the analysis is based on a unit other than participants, a description of the unit of analysis and the number of units for which an outcome was measured and analyzed, by arm or comparison group.

(C) Analysis Population Description. If the Number of Participants Analyzed differs from the number of human subjects assigned to the arm or comparison group, a brief description of the reason(s) for the difference.

(iii) *Outcome Measure Information.* A description of each outcome measure, to include the following elements:

(A) Name of the specific outcome measure, including the titles of any categories in which Outcome Measure Data are aggregated;

(B) Description of the metric used to characterize the specific outcome measure;

(C) Time point(s) at which the measurement was assessed for the specific metric;

(D) Outcome Measure Type. The type of outcome measure, whether primary, secondary, other pre-specified, or post-hoc;

(E) *Outcome Measure Reporting Status.* Whether data for the outcome measure are included in the present submission and, if not, the anticipated submission date;

(F) *Measure Type.* For each outcome measure for which data are collected, the type of data to be submitted (number or measure of central tendency) and, if a measure of central tendency, the related measure of dispersion or precision;

(G) *Unit of Measure.* For each outcome measure for which data are collected, the unit of measure.

(iv) *Outcome Measure Data.* The measurement value(s) for each outcome measure for which data are collected, by arm or comparison group, and by category (if specified).

(v) *Statistical Analyses.* Result(s) of scientifically appropriate statistical analyses, if any, including any statistical analysis that is:

(A) Pre-specified in the protocol and/or statistical analysis plan that was performed on the outcome measure data,

(B) Made public by the sponsor or responsible party prior to the date on which results information is submitted for all primary and secondary outcome measures studied in the clinical trial, or

(C) Conducted in response to a request made by the U.S. Food and Drug Administration prior to the date on which complete clinical trial results information is submitted for all of the primary outcome measures studied in the clinical trial. Submitted Statistical Analysis information must include:

(*1*) *Statistical Analysis Overview:* Identification of the arms or comparison groups compared in the statistical analysis, the type of statistical test conducted; and, for a non-inferiority test, a description of the analysis that includes, at minimum, the power calculation and non-inferiority margin;

(*2*) *Statistical Test of Hypothesis:* The p-value and the procedure used for the statistical analysis;

(*3*) *Method of Estimation:* The estimation parameter, estimated value, and confidence interval.

(4) *Adverse event information.* (i) Information for completing two tables summarizing adverse events collected during an applicable clinical trial:

(A) Table of all serious adverse events grouped by organ system, with the number and frequency of each event by arm or comparison group; and

(B) Table of all adverse events, other than serious adverse events, that exceed a frequency of 5 percent within any arm of the clinical trial, grouped by organ system, with the number and frequency of each event by arm or comparison group.

(ii) Information for each table specified in paragraph (a)(4)(i) of this section must include the following elements:

(A) *Adverse Event Arm/Comparison Group Information.* A brief description of each arm or comparison group used for submitting adverse event information from the clinical trial, including a descriptive title used to identify each arm or comparison group.

(B) *Total Number Affected, by Arm or Comparison Group.* The overall number of human subjects affected, by arm or comparison group, by one or more

(*1*) Serious adverse event(s), or

(*2*) Adverse event(s) other than serious adverse events that exceed a frequency of 5 percent within any arm of the clinical trial.

(C) *Total Number at Risk, by Arm or Comparison Group.* The overall number of human subjects included in the assessment, by arm or comparison group, for

(*1*) Serious adverse events, or

(*2*) Adverse event(s) other than serious adverse events that exceed a frequency of 5 percent within any arm of the clinical trial.

(D) *Total Number Affected, by Organ System.* For each organ system that has one or more adverse events listed in either the table of serious adverse events or the table of adverse events other than serious adverse events that exceed a frequency of 5 percent within any arm of the clinical trial, the overall number of human subjects affected, by arm or comparison group, within each table.

(E) *Total Number at Risk, by Organ System.* For each organ system that has one or more adverse events listed in either the table of serious adverse events or the table of adverse events other than serious adverse events that exceed a frequency of 5 percent within any arm of the clinical trial, the overall number of human subjects at risk for the adverse event, by arm or comparison group.

(F) *Adverse Event Information.* A description of each type of serious adverse event and other adverse event that is not a serious adverse event and exceeds a frequency of 5 percent within any arm of the clinical trial, consisting of the following attributes:

(*1*) Descriptive term for the adverse event; and

(*2*) Organ system associated with the adverse event.

(G) *Adverse Event Data.* For each type of adverse event listed in accordance with paragraph (a)(4)(ii)(F) of this section:

(*1*) Number of human subjects affected by such adverse event;

(*2*) Number of human subjects at risk for such adverse event;

(H) *Additional Adverse Event Description.* If the adverse event information collected in the applicable clinical trial is collected based on a different definition of adverse event and/or serious adverse event than defined in this part, a brief description of how those definitions differ.

(iii) Information submitted by organ system must be grouped according to the organ system classification established in ClinicalTrials.gov.

(5) *Administrative information.* (i) *Results Point of Contact.* Point of contact for scientific information about the clinical trial results information, including the following:

(A) Name or official title of the point of contact;

(B) Name of affiliated organization; and

(C) Telephone number and email address of the point of contact.

(ii) *Certain Agreements.* An indication of whether the principal investigator is an employee of the sponsor and, if not, whether there exists any agreement (other than an agreement solely to comply with applicable provisions of law protecting the privacy of human

subjects participating in the clinical trial) between the sponsor or its agent and the principal investigator that restricts in any manner the ability of the principal investigator, after the completion date of the clinical trial, to discuss the results of the clinical trial at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the clinical trial.

(6) *Additional clinical trial results information for applicable device clinical trials of unapproved or uncleared devices.* (i) For an applicable device clinical trial of an unapproved or uncleared device, the responsible party must provide the following data elements, as the data elements are defined in § 11.10(b): Brief Title; Official Title; Brief Summary; Primary Purpose; Study Design; Study Type; Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study; Intervention Name; Other Intervention Name; Intervention Description; Intervention Type; U.S. FDA Approval, Licensure, or Clearance Status; Study Start Date; Completion Date; Enrollment; Primary Outcome Measure Information, as previously submitted to ClinicalTrials.gov; Secondary Outcome Measure Information as previously submitted to ClinicalTrials.gov; Eligibility Criteria; Gender; Age Limits; Accepts Healthy Volunteers; Overall Recruitment Status; Why Study Stopped; Actual Enrollment; Name of the Sponsor; Responsible Party by Official Title; Facility Name and Facility Location, for each participating facility in a clinical trial; Unique Protocol Identification Number; Secondary IDs; Human Subjects Protection Review Board Status; and Record Verification Date.

(ii) The responsible party shall submit the results information specified in paragraph (a)(6)(i) of this section by submitting an affirmation that the information previously submitted to ClinicalTrials.gov for the data elements listed in paragraph (a)(6)(i) of this section have been updated in accordance with § 11.64(c) and are to be included as clinical trial results information.

(b) *Pediatric postmarket surveillance of a device that is not a clinical trial.* For each pediatric postmarket surveillance of a device that is not a clinical trial, the responsible party must submit a copy of any written final report that is submitted to FDA as specified in 21 CFR 822.38 (or any successor regulation). The final written report must be in a common electronic document format specified at *http://prsinfo.clinicaltrials.gov.* The responsible party must redact names, addresses, and other personally identifiable information or commercial confidential information contained in the final written report prior to submission to NIH. Redacted information may not include any information specified in §§ 11.28(a) or 11.48(a) of this part.

§ 11.52 When will NIH post submitted clinical trial results information?

The Director will post publicly clinical trial results information submitted under this subpart at ClinicalTrials.gov not later than 30 calendar days after the date of submission.

§ 11.54 What are the procedures for waiving of the requirements of this subpart?

(a) Waiver request.

(1) A responsible party may request a waiver from any applicable requirement(s) of this subpart by submitting a waiver request in the form of a written letter to the Secretary or delegate prior to the deadline specified in § 11.42(a) for submitting clinical trial results information.

(2) The waiver request must contain:

(i) The NCT number, Brief Title, and Name of the Sponsor of the applicable clinical trial for which the waiver is requested;

(ii) The specific requirement(s) of this subpart for which the waiver is requested; and

(iii) A description of the extraordinary circumstances that the responsible party believes justify the waiver and an explanation of why granting the request would be consistent with the protection of public health or in the interest of national security.

(3) The responsible party will not be required to comply with the specified requirements of this subpart for which a waiver is granted.

(4) The responsible party must comply with any requirements of this subpart for which a waiver is not granted or must submit an appeal as set forth in paragraph (b) of this section. The deadline for submitting any required clinical trial results information will be the later of the original submission deadline or 15 calendar days after the notification of the denial is sent to the responsible party.

(b) Appealing a denied waiver request

(1) A responsible party may appeal a denied waiver request by submitting a letter in writing to the Secretary or delegate not later than 15 calendar days after the date on which the letter in paragraph (a)(iii) of this section denying the request is transmitted.

(2) The responsible party is not required to comply with any requirements of this subpart for which the waiver is granted upon appeal.

(3) The responsible party must submit clinical trial results information to comply with any requirements of this subpart that are not waived upon appeal by the later of the original submission deadline or 15 calendar days after the written notice of the denial upon appeal is sent by the Secretary.

(c) If a waiver is granted under paragraph (a) or (b) of this section,

(1) The Director will include a notation in the clinical trial record that specified elements of the requirements of this part have been waived.

(2) The Secretary will notify, in writing, the appropriate committees of Congress and provide an explanation for why the waiver was granted, not later than 30 calendar days after any part of a waiver is granted.

Subpart D—Additional Submissions of Clinical Trial Information

§ 11.60 What requirements apply to the voluntary submission of clinical trial information for clinical trials of FDA-regulated drugs and devices?

(a) If a responsible party voluntarily submits clinical trial information for a clinical trial described in paragraph (a)(1) of this section, the responsible party must meet the conditions specified in paragraph (a)(2) of this section.

(1) Clinical trials to which this section applies. The requirements of this section apply to the following types of clinical trials:

(i) A clinical trial of an FDA-regulated drug or device that is not an applicable clinical trial, and

(ii) An applicable clinical trial that is not required to submit clinical trial registration information under § 11.22(a).

(2) Conditions for voluntary submission of certain clinical trials. The following conditions must be met by a responsible party who voluntarily submits clinical trial information for a clinical trial that is described in paragraph (a)(1) of this section.

(i) The responsible party must submit the information in (A) or (B) for the clinical trial being submitted voluntarily.

(A) If the responsible party voluntarily registers a clinical trial, the responsible party must submit complete clinical trial registration information specified in § 11.28(a). The responsible party may, but is not required to, submit

complete clinical trial results information in § 11.48(a).

(B) If the responsible party voluntarily submits clinical trial results information for a clinical trial for which the clinical trial registration information specified in § 11.28(a) has not been submitted, the responsible party must submit the data elements specified in § 11.48(a), as well as the data elements listed below, as those the data elements are defined in § 11.10(b) and apply to the clinical trial and the interventions studied: Brief Title; Official Title; Brief Summary; Primary Purpose; Study Design; Study Phase, for a clinical trial of a drug; Study Type; Whether the Study is a Pediatric Postmarket Surveillance of a Device; Primary Disease or Condition Being Studied in the Trial; or the Focus of the Study; Intervention Name, for each intervention studied; Other Intervention Name, for each intervention studied; Intervention Description, for each intervention studied; Intervention Type, for each intervention studied; U.S. FDA Approval, Licensure, or Clearance Status, for each intervention studied; Product Manufactured in the U.S., for each intervention studied; Studies an FDA-regulated Device; Studies an FDA-regulated Drug; Study Start Date; Completion Date; Enrollment; Eligibility Criteria; Gender; Age Limits; Accepts Healthy Volunteers; Overall Recruitment Status; Why Study Stopped; Actual Enrollment; Availability of Expanded Access; Name of the Sponsor; Responsible Party by Official Title; Facility Name and Facility Location, for each participating facility; Unique Protocol Identification Number; Secondary IDs; Food and Drug Administration IND or IDE Number; Human Subjects Protection Review Board Status; Record Verification Date; and Responsible Party Contact Information.

(ii) If, on or after September 27, 2007, a manufacturer submits an application or premarket notification to FDA for approval, licensure, or clearance of a drug or device under sections 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act for the use studied in the clinical trial submitted under paragraph (a)(1) of this section, the Responsible Party specified in paragraph (a)(1) of this section must also submit the information specified in paragraph (a)(2)(iii) of this section by the deadline specified in paragraph (a)(2)(iv)(B) of this section for any applicable clinical trial that has not been submitted to ClinicalTrials.gov and that meets the following criteria:

(A) The applicable clinical trial is required to be submitted to FDA under sections 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act in an application or premarket notification for approval, licensure, or clearance to market the drug or device for the use studied in the clinical trial specified in paragraph (a)(1) of this section; and

(B) The manufacturer of the drug or device studied in the applicable clinical trial is also the responsible party for the clinical trial specified in paragraph (a)(1) of this section.

(iii) Information to be submitted for clinical trials described in paragraph (a)(2)(ii) of this section:

(A) If the clinical trial information voluntarily submitted for a clinical trial described in paragraph (a)(1) of this section consists only of the clinical trial registration information specified in § 11.28(a), then the information to be submitted in accordance with paragraph (a)(2)(ii) of this section must consist, at minimum, of the clinical trial registration information specified in § 11.28(a).

(B) If the clinical trial information voluntarily submitted for a clinical trial described by paragraph (a)(1) of this section consists of the clinical trial results information specified in § 11.60(a)(2)(i)(B), then the information to be submitted in accordance with paragraph (a)(2)(ii) of this section must consist of the clinical trial results information specified in § 11.60(a)(2)(i)(B).

(C) If the clinical trial information voluntarily submitted for a clinical trial described by paragraph (a)(1) of this section consists of both the clinical trial registration information specified in § 11.28(a) and the clinical trial results information specified in § 11.48(a), then the information to be submitted in accordance with paragraph (a)(2)(ii) of this section must consist of the clinical trial registration information specified in § 11.28(a) and the clinical trial results information specified in § 11.48(a).

(iv) Submission deadlines:

(A) Secondary outcome measure(s) for voluntarily-submitted clinical trials under paragraph (a) of this section. If data collection for the secondary outcome measure(s) for a voluntarily-submitted clinical trial under paragraph (a) of this section, which submission consists of clinical trial results information, is not completed by the completion date of the voluntarily-submitted clinical trial, then clinical trial results information for the secondary outcome measure(s) must be submitted by the later of the date that the clinical trial results information is voluntarily submitted for the primary outcome measure(s) or 1 year after the date on which the final subject was examined or received an intervention for the purposes of final collection of data for the secondary outcome(s), whether the clinical trial was concluded according to the pre-specified protocol or was terminated.

(B) The clinical trial information specified in paragraph (a)(2)(iii) of this section must be submitted not later than the later of the date on which the application or premarket notification to FDA for approval, licensure, or clearance to market a drug or device under section 351 of the Public Health Service Act or sections 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act for the use studied in the clinical trial specified under paragraph (a)(1) of this section is submitted to FDA; or, the date on which the clinical trial information specified in paragraph (a)(2)(i) of this section for the clinical trial specified under paragraph (a)(1) of this section is submitted to ClinicalTrials.gov.

(v) All submissions of clinical trial information under paragraph (a) of this section are subject to the update requirements specified in § 11.64 and the corrections requirements specified in § 11.66.

(b) Statement to accompany applicable clinical trials submitted under paragraph (a) of this section. Each applicable clinical trial for which clinical trial information is submitted under paragraph (a) of this section and posted at ClinicalTrials.gov will include the statement ''Clinical trial information for this applicable clinical trial was submitted under section 402(j)(4)(A) of the Public Health Service Act and 42 CFR 11.60 and is not subject to the deadlines established by sections 402(j)(2) and (3) of the Public Health Service Act or 42 CFR 11.24 and 11.44.''

§ 11.62 What requirements apply to applicable clinical trials for which submission of clinical trial information has been determined by the Director to be necessary to protect the public health?

(a) A responsible party who receives notification that the Director has determined that posting of clinical trial information for an applicable clinical trial described in paragraph (b) of this section is necessary to protect the public health must submit clinical trial information as specified in paragraph (c) of this section.

(b) An applicable clinical trial subject to this section must be either:

(1) An applicable clinical trial of an approved, licensed, or cleared drug or

device that has a completion date on or after September 27, 1997; or

(2) An applicable clinical trial that is subject to registration under § 11.22(a) and studies a drug or device that is unapproved, unlicensed, or uncleared.

(c) Deadline for submission of clinical trial information.

(1) *General.* Except as provided in paragraphs (c)(2) and (c)(3) of this section, a responsible party for an applicable clinical trial that is subject to this section must submit clinical trial registration information specified in § 11.28(a) and clinical trial results information specified in § 11.48(a) to ClinicalTrials.gov not later than 30 calendar days after the submission date specified in the notification described in paragraph (a) of this section.

(2) *Exception.* If a responsible party submits a certification consistent with § 11.44(b) or (c) not later than 30 calendar days after the submission date specified in the notification described in paragraph (a) of this section, the responsible party must submit clinical trial results information specified in § 11.48(a) not later than the deadline specified in § 11.44(b) or (c), as applicable.

(3) If a responsible party submitted clinical trial registration information describing the applicable clinical trial specified in the notification described in paragraph (a) of this section prior to the date on which the notification is sent to the responsible party, the responsible party must update such clinical trial information to reflect changes, if any, in the applicable clinical trial not later than 30 calendar days after the submission date specified in the notification described in paragraph (a) of this section, irrespective of the deadline for updates specified in § 11.64.

§ 11.64 When must clinical trial information submitted to ClinicalTrials.gov be updated?

(a) *General.* (1) Except as provided in paragraphs (b) and (c) of this section, the responsible party for an applicable clinical trial or other clinical trial must submit updates to reflect changes to previously-submitted clinical trial information not less than once every 12 months, unless there are no changes to the clinical trial information during the preceding 12-month period.

(2) Updates to the estimated Completion Date must be submitted not less than once every 12 months, unless there is no change to the estimated date during the preceding 12-month period.

(3) A responsible party must continue to submit updates as specified in this section until the date on which complete clinical trial results information specified in § 11.48 has been submitted for all primary and secondary outcomes and all adverse events that were collected in accordance with the protocol.

(b) *Items Requiring More Rapid Updates.* (1) A responsible party must submit updates to reflect changes to the following clinical trial information data elements not later than 30 calendar days after the change has occurred:

(i) If the first human subject was not enrolled in the clinical trial at the time of registration, the Study Start Date data element must be updated not later than 30 calendar days after the first human subject is enrolled.

(ii) Intervention Name(s) must be updated to a non-proprietary name not later than 30 calendar days after a non-proprietary name is established for any intervention included in the Intervention Name(s) data element.

(iii) *Availability of Expanded Access.* (A) If expanded access to a drug becomes available after a clinical trial of that drug has been registered, the responsible party must, not later than 30 calendar days after expanded access becomes available, update the Availability of Expanded Access data element for that clinical trial and, unless an expanded access record has already been created as required by § 11.28(a)(2)(ix), submit the data elements listed in § 11.28(c) to create an expanded access record.

(B) Upon receipt of an NCT number for an expanded access record created for a clinical trial under § 11.28(a)(2)(ix), the responsible party must update the Availability of Expanded Access data element by entering in the clinical trial record the NCT number of the expanded access record no later than 30 calendar days after the date on which the responsible party receives such NCT number.

(C) Upon termination of an expanded access program, the responsible party must, not later than 30 calendar days after the date of termination, update the Availability of Expanded Access data element to indicate that expanded access is no longer available.

(iv) Expanded Access Status, under § 11.28(c)(2)(iv), must be updated not later than 30 calendar days after a change in the availability of access to an investigational drug or investigational device under section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb).

(v) Overall Recruitment Status must be updated not later than 30 calendar days after any change in overall recruitment status. At the time Overall Recruitment Status is changed, the responsible party must also make the following updates, as applicable:

(A) If Overall Recruitment Status is changed to ''suspended,'' ''terminated,'' or ''withdrawn,'' the Why Study Stopped data element must be submitted.

(B) If Overall Recruitment Status is changed to ''terminated'' or ''active, not recruiting,'' the Actual Enrollment data element must be submitted.

(vi) Individual Site Status must be updated not later than 30 calendar days after a change in status of any individual site.

(vii) Human Subjects Protection Review Board Status must be updated not later than 30 calendar days after a change in status.

(viii) Completion Date must be updated not later than 30 calendar days after the clinical trial reaches its actual completion date;

(ix) Responsible Party, by Official Title must be updated not later than 30 calendar days after a change in the responsible party or the official title of the responsible party;

(x) Responsible Party Contact Information must be updated not later than 30 calendar days after a change in the responsible party or the contact information of the responsible party;

(2) Updates to the U.S. FDA Approval, Licensure, or Clearance Status data element must be submitted not later than 15 calendar days after a change in status has occurred.

(3) If a protocol is amended in such a manner that changes are communicated to human subjects in the clinical trial, updates to relevant clinical trial information data elements must be submitted no later than 30 calendar days after the protocol amendment is approved by a human subjects protection review board.

(4) Record Verification Date must be updated any time the responsible party reviews the complete set of submitted clinical trial information for accuracy, even if no other updated information is submitted at that time.

(c) Irrespective of update requirements established in paragraphs (a) and (b) of this section, upon submission of clinical trial results information for an applicable clinical trial or other clinical trial, a responsible party must submit updates to the clinical trial registration information submitted previously to ClinicalTrials.gov for that applicable clinical trial or other clinical trial, unless there are no changes to the clinical trial registration information.

(d) Public availability of updates.

(1) Updates to clinical trial registration information and clinical

trial results information will be posted in accordance with § 11.35 and § 11.52, respectively.

(2) The Director will retain prior clinical trial registration information and clinical trial results information and make it publicly available in accordance with § 11.35 and § 11.52, respectively, through ClinicalTrials.gov so that the updates do not result in the removal of any information from the original submission or any preceding update.

§ 11.66 What are the requirements for corrections of clinical trial information?

(a) *Correction of errors.* A responsible party who becomes aware of errors in any clinical trial information submitted under this part or is informed by NIH that such clinical trial information contains errors shall correct such errors not later than 15 calendar days after the date on which the responsible party becomes aware of the errors or on which NIH informs the responsible party of the errors, whichever is earlier.

(b) *Correction of falsified data.* A responsible party who becomes aware that clinical trial information submitted under this part was falsified or based on falsified information, shall notify the Director that such information was determined to be falsified or based on falsified information and either:

(1) Submit corrected clinical trial information not later than 15 calendar days after corrected information becomes available; or

(2) Notify the Director not later than 15 calendar days after determining that such information cannot be corrected or is correct as submitted.

(c) *Other corrections of clinical trial information.* A responsible party who becomes aware or is informed by NIH that corrections other than those specified in paragraphs (a) or (b) of this section are needed to any clinical trial information submitted under this part, shall correct such clinical trial information as soon as possible, but not later than 15 calendar days after the date on which the responsible party becomes aware, or is informed by NIH that such clinical trial information is in need of correction, whichever is earlier.

Dated: October 7, 2014.

Francis S. Collins,

Director, National Institutes of Health.

Approved: October 28, 2014.

Sylvia Mathews Burwell,

Secretary.

[FR Doc. 2014–26197 Filed 11–19–14; 11:15 am]

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Part III

Federal Communications Commission

47 CFR Part 64
Rates for Interstate Inmate Calling Services; Second Further Notice of Proposed Rulemaking; Proposed Rule

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[WCB: WC Docket No. 12–375; FCC 14–158]

Rates for Interstate Inmate Calling Services; Second Further Notice of Proposed Rulemaking

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission seeks comment on additional measures it could take to ensure that interstate and intrastate inmate calling services are provided consistent with the statute and the public interest and the Commission's authority to implement these measures. The Commission believes that additional action on inmate calling service will help maintain familial contacts stressed by confinement while still ensuring the critical security needs of correction facilities of various sizes.

DATES: Comments are due on or before January 5, 2015. Reply comments are due on or before January 20, 2015.

ADDRESSES: You may submit comments, identified by WC Docket 12–375, by any of the following methods:

- Federal Communications Commission's Web site: *http://fjallfoss.fcc.gov/ecfs2/.* 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.

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: Lynne Engledow, Pricing Policy Division, Wireline Competition Bureau, 202–418–1520 or *Lynne.Engledow@fcc.gov.*

SUPPLEMENTARY INFORMATION: 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).

This is a summary of the Commission's Second Further Notice of Proposed Rulemaking released on October 23, 2014. This document does not contain information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified ''information collection burden for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002. A full text of this document is available at the following Internet address: *http://www.fcc.gov/document/fcc-continues-push-rein-high-cost-inmate-calling-0.* The complete text may be purchased from Best Copy and Printing, Inc., 445 12th Street SW., Room CY–B402, Washington, DC 20554. Public and agency comments are due January 5, 2015.

I. Introduction

1. In 2013, nearly ten years after Martha Wright, a grandmother from Washington, DC, petitioned the Federal Communications Commission (Commission or FCC) for relief from exorbitant long-distance calling rates from correctional facilities, the Commission took long overdue steps to provide relief to the millions of Americans paying unjust and unreasonable interstate inmate phone rates. These exorbitantly high rates discouraged phone calls and, at times, made it nearly impossible for inmates to maintain contact with their families, friends and communities, to society's detriment.

2. Reforming inmate calling service (ICS) benefits society by making it easier for inmates to stay connected to their families and friends. An April 2014 report from the Department of Justice found that, of the 400,000 prisoners released over a five-year period, two-thirds were rearrested within three years, and three-quarters were rearrested within five years. As a nation, we need to take all actions possible to reduce these recidivism rates. Studies have shown that family contact during incarceration is associated with lower recidivism rates. Lower recidivism means fewer crimes, decreases the need for additional correctional facilities, and reduces the overall costs to society. Reform also helps families and the estimated 2.7 million children of incarcerated parents in our nation, an especially vulnerable part of our society. In addition to coping with the anxiety associated with a parent who is not present on a daily basis, these young people are often suffering severe economic and personal hardships and are often doing poorly in school, all of which are exacerbated by the inability to maintain contact with their incarcerated parent due to unaffordable inmate calling rates.

3. While the Commission prefers to promote competition to ensure rates are just and reasonable, it remains clear that in the inmate calling service market, as currently structured, competition is failing to do so. Evidence in the record indicates that, as of 2013, interstate ICS rates with comparable security features and protections varied from as low as $0.046 per minute to as high as $0.89 per minute, plus a per call charge as high as $3.95. Even worse, rates are as high as $2.26 per minute for a call placed by a deaf or hard of hearing prisoner. Excessive rates are primarily caused by the widespread use of site

commission payments—fees paid by ICS providers to correctional facilities or departments of corrections to win the exclusive right to provide inmate calling service at a facility. These site commission payments, which have recently been as high as 96% of gross revenues, inflate rates and fees, as ICS providers must increase rates in order to pay the site commissions. This forces inmates and their friends and families, who use ICS and are forced to absorb the site commissions in the rates they pay, to subsidize everything from inmate welfare programs, to salaries and benefits of correctional facilities, states' general revenue funds, and personnel training. The ICS market has been characterized by some as subject to ''reverse competition,'' forcing providers to compete not on price or service quality but on the size of site commission payments—a dynamic that drives rates ever higher to cover greater and greater site commission payments.

4. The 2013 *Inmate Calling Report and Order and FNPRM* tackled these issues for the first time and took important initial steps for reform. The Order adopted a cost-based approach with interim interstate rate caps and a Mandatory Data Collection to allow the Commission to evaluate ICS costs, including ancillary charge costs, in order to develop reforms such as permanent rate caps and to address the use of ancillary charges not reasonably related to the cost of providing service. With regard to site commission payments, the Order reaffirmed the Commission's previous holding that site commission payments are an apportionment of profit. The Order also determined that site commission payments and other provider expenditures not reasonably related to the provision of interstate ICS are not recoverable through ICS rates.

5. Although the rate caps adopted in the Order were interim in nature pending results of the Mandatory Data Collection, the reforms have already had a significant impact on contact between inmates and their families. Evidence indicates that as interstate rates have declined, there has been a corresponding increase in call volumes. For example, one provider indicates that, as a result of the Commissions' reforms, its interstate ICS rates declined 39 percent and interstate call volumes increased 20 to 30 percent. Praeses reports that it tracked interstate ICS call volume for its clients and that in comparing a four-month period prior to the *Inmate Calling Report and Order and FNPRM* with another period one year later, post-adoption, ''call volume increased nearly seventy percent.'' But interstate rates are only part of the ICS market. Although the Order set a framework for states to follow, few have done so. Many intrastate rates remain high, with some having even increased following the Order. There are indications that ancillary fees have also increased in number, price, or both, leading to further expense for ICS consumers in a manner that is often unrelated to the cost of providing ICS. These developments underscore the critical need for the Commission to move expeditiously to adopt comprehensive, permanent reforms.

6. The Commission was unable to adopt comprehensive reform in the *Inmate Calling Report and Order and FNPRM* due to the limited data in the record and administrative notice limited only to interstate ICS. Because we seek comment on a comprehensive solution—rather than just reforming interstate rates—we seek comment on moving to a market-based approach to encourage competition in order to reduce rates to just and reasonable levels and to ensure fair but not excessive ICS compensation. This approach was not feasible when the Commission previously addressed interstate rates because new intrastate rates and fees could circumvent such efforts. We therefore initiate this Second Further Notice of Proposed Rulemaking (Second Further Notice) to develop a record to adopt comprehensive, permanent ICS reforms as expeditiously as possible. In this item, we seek comment on adopting a simplified, market-based approach focused on aligning the interests of ICS providers and facilities to deliver high quality ICS with advanced security features at the lowest prices for end users. We seek comment on whether such an approach will significantly limit competitive distortions in the ICS marketplace. We seek comment on the Commission's legal authority regarding site commissions and ask whether such payments should be prohibited. We seek comment on whether facilities incur costs in the provision of ICS and, if so, how facilities should recover these costs, as well as appropriate transition periods to enable facilities time to adjust. We seek comment on proposals in the record to establish permanent rate caps for all intrastate and interstate calls, limit ancillary charges, and adopt other measures to ensure that ICS rates are just, reasonable, fair, and accessible to all Americans. We believe that this market-based approach is only possible through a comprehensive reform effort dealing with all of the major portions of the ICS market, unlike when the Commission addressed only interstate ICS in the *Inmate Calling Report and Order and FNPRM.* We seek comment on alternative ways to promote competition in the ICS market. We seek comment on whether eliminating site commissions and capping rates and fees, on both interstate and intrastate ICS, better aligns the interests of both ICS providers and correctional institutions with the interests of consumers, allowing market forces to drive rates to competitive levels.

II. Background

7. In 2003, Mrs. Wright and her fellow petitioners (Wright Petitioners or Petitioners), who included current and former inmates at Corrections Corporations of America-run confinement facilities, filed a petition with the Commission seeking to initiate a rulemaking to address high long-distance ICS rates. The petition sought to prohibit exclusive ICS contracts and collect-call-only restrictions in correctional facilities. In 2007, the same petitioners filed an alternative rulemaking petition, asking the Commission to address high ICS rates by requiring a debit-calling option in correctional facilities, prohibiting per-call charges, and establishing rate caps for interstate, interexchange ICS. The Commission sought and received comment on both petitions.

8. In December 2012, the Commission adopted a notice of proposed rulemaking seeking comment on, among other things, the proposals in the Wright petitions. The *2012 ICS NPRM* sought comment on the two petitions and proposed ways to ''balance the goal of ensuring reasonable ICS rates for end users with the security concerns and expense inherent to ICS within the statutory guidelines of sections 201(b) and 276 of the Act.'' The *2012 ICS NPRM* sought comment on other issues affecting the ICS market, including possible rate caps for interstate ICS; ancillary charges; data in the record; collect, debit, and prepaid ICS calling options; site commissions; issues regarding disability access; and the Commission's statutory authority to regulate ICS.

9. On August 9, 2013, the Commission adopted the *Inmate Calling Report and Order and FNPRM,* finding that interstate ICS rates were not just and reasonable as required by section 201 of the Act, and did not ensure fair, and not excessive, compensation for ICS providers as required by section 276 of the Act. In response, the Commission adopted reforms to ensure interstate rates were just, reasonable, and fair as required by Sections 201 and 276 and

focused on reforming interstate site commission payments, rates, and ancillary charges. The Commission concluded that, in the absence of competitive pressures, the default of cost-based regulation should apply to the ICS market. As discussed in the *Order,* this approach is consistent with Commission practice that ''typically focuses on the costs of providing the underlying service when ensuring that rates for service are just and reasonable under section 201(b).'' In addition, the Commission noted that ''the cost of providing payphone service generally has been a key point of reference when [it] evaluates rules implementing the fair compensation requirements of section 276(b)(1)(A).''

10. The Commission reaffirmed previous findings that site commission payments were not costs but ''profit.'' As a result, the Commission determined that site commission payments ''were not part of the cost of providing ICS and therefore not compensable in interstate ICS rates'' The Commission's previous request for ''updated data from all interested parties and the public, but especially from ICS providers . . . to aid . . . in developing a clearer understanding of the ICS market,'' went largely unheeded. Therefore, the Commission analyzed the limited data submitted by ICS providers, in addition to publicly-available data, to establish interim per-minute interstate ICS safe harbor caps of $0.12 and $0.14 and hard rate caps of $0.21 for debit and prepaid calls and $0.25 for collect calls to ensure that all rates were reduced, and provided guidance about the waiver process for ICS providers that could show good cause. The Commission also required that ancillary charges be cost based. Finally, the Commission chose not to address intrastate ICS, noting instead that it had ''structured [its reforms] in a manner to encourage . . . states to undertake reform.'' It noted, however, that in the absence of state reform of intrastate ICS, unreasonably high rates would likely continue, which would require the Commission to ''take action to reform unfair intrastate ICS rates.''

11. The changes to interstate rates adopted by the Commission were significant but interim. To enable the Commission to adopt permanent ICS reform, the Commission adopted a Mandatory Data Collection for ICS providers to report costs and an Annual Reporting and Certification Requirement of ICS rates. In the *FNPRM* the Commission sought specific comment on multiple aspects of permanent ICS reform regardless of jurisdiction or call type.

12. Prior to the effective date of the *Order,* the DC Circuit stayed three rules adopted by the Commission pending resolution of the appeal, including the rule requiring rates to be based on costs, the rule adopting an interim safe harbor, and the rule requiring ICS providers to file annual reports and certifications. The court allowed other aspects of the *Order* to take effect, including the interim interstate rate caps.

13. Since the adoption of the *Order,* the Commission has continued to monitor the effect of its reforms on the ICS industry and pursue additional reform, including holding a workshop entitled ''Further Reform of Inmate Calling Services'' on July 9, 2014. The workshop evaluated options for additional ICS reforms, discussed the effects of the *Order,* the role ancillary charges play in the ICS market, the provision of ICS at different types of facilities, and communications technologies beyond traditional payphone calling being deployed in correctional facilities.

14. On June 11, 2014, the Commission received approval for its Mandatory Data Collection from the Office of Management and Budget, and, after publication in the **Federal Register**, announced in a Public Notice that data responses were due on July 12, 2014, a date which was subsequently extended until August 18, 2014. In response, the Commission received significant cost and operational data, including ancillary charge cost data, from the following ICS providers: ATN, CenturyLink, Combined Public Communications, Correct Solutions, Custom Teleconnect, Encartele, GTL, Lattice, ICSolutions, NCIC, Pay Tel Communications, Protocall, Securus, and Telmate. Collectively, these providers represent the vast majority, well over 85 percent, of the ICS market. In this Second Further Notice, we seek comment on these data, including some reporting and cost allocation inconsistencies among the providers. We seek comment on these issues and generally on the data received as we propose to move forward and adopt permanent interstate and intrastate ICS reform.

15. *Proposals for Reform in the Record.* Since the *Order,* we have received several proposals in the record urging comprehensive ICS reform. On September 15, 2014, GTL, Securus, and Telmate, who claim to be ''the primary providers of inmate calling services . . . in the United States and representing 85% of the industry revenue in 2013,'' jointly filed a proposal to comprehensively reform all aspects of ICS. First, the Joint Provider Reform Proposal urges the adoption of rate caps of $0.20 per minute for debit and prepaid interstate and intrastate ICS, and $0.24 per minute for all interstate and intrastate collect ICS, effective 90 days after adoption of a final order. The Joint Provider Reform Proposal supports ''reductions in site commission payments'' but does not specify exactly what such reductions would entail. The Proposal suggests the prohibition of ''in-kind payments, exchanges, technology allowances, administrative, fees,'' or anything ''not directly related to, or integrated with, the provision of ICS.'' These three ICS providers contend that the Commission does not have authority over ''ancillary fees for transactions other than the provision of ICS'' but propose to eliminate some ancillary fees, limit allowable ancillary fees to those specified in the document, and cap other ancillary fees. Finally, these three ICS providers ''commit to continue to comply with their existing obligations'' under the Americans with Disabilities Act and other statutes for inmates with disabilities, and suggest that the Commission require officers of ICS providers to certify compliance with all adopted rules under penalty of perjury. GTL, a signatory of the Proposal, later characterized the Proposal as ''part of a new framework that is designed to respond to market forces'' and noted that ''[t]he proposed rates and fees are caps, which can vary by contract based on the correctional facility needs and the bidding process.''

16. In addition to the Joint Provider Reform Proposal, several individual ICS providers also submitted proposals for reform. CenturyLink asserts that it could ''support a unified cap approximately at the current interstate cap levels,'' which would apply ''for both interstate and intrastate calls, with an additional allowance for collect calling.'' CenturyLink supports a prohibition on ''all or all but a very narrow class of ancillary fees.'' CenturyLink also asserts that the Commission should ''allow reasonable commissions or administrative fees,'' exempt from regulation high-cost facilities such as secure mental health facilities, and grandfather existing contracts. Pay Tel also submitted a proposal for reform, which it characterizes as a ''comprehensive solution to ICS reform that attempts to be fair to all affected parties, including inmates and their families, facilities, and vendors.'' Pay Tel's Proposal suggests ''postalized'' per-minute rate caps, at a rate to be determined, for both intrastate and interstate calls, separated between

prisons and jails, with no per-call charges allowed. Specific ancillary fees would be allowed, with some ''premium calling options'' for jails, and all other ancillary fees prohibited. Pay Tel proposes that all facilities would be required to comply with existing obligations and laws regarding people with disabilities.

17. The Wright Petitioners, along with several public interest groups, urge the Commission to adopt a $0.07 per minute rate cap for all interstate debit, prepaid, and collect calls, with no per-minute rate, and no other ancillary fees or taxes allowed. Prisoners' Legal Service of MA (PLS) contends that the interim safe harbors and caps that the Commission implemented in the *Order* are conservative and ''exceed cost data that any party submitted in the record.'' PLS opposes extending the interim safe harbor rates and caps, and instead proposes that the Commission adopt a flat all-distance rate of $0.07 per minute, regardless of the size of the facility or the call volume generated from the facility. To justify this rate, PLS points to the fact that ICS providers are charging as low as $0.04 and $0.05 per minute absent commissions in some states.

18. A few states have undertaken ICS reform since the Commission's *Order.* The Alabama Public Service Commission (Alabama PSC) recently adopted comprehensive ICS reforms that include intrastate rate caps as well as restrictions on the number and rates of ancillary charges it authorized. The Minnesota Department of Corrections initiated a pilot program in a limited number of correctional facilities in which a flat rate of $0.07 per minute is charged for all local and long-distance debit calls, bringing the cost of a 15-minute call to $1.05, plus applicable tax. New Jersey recently lowered ICS rates to $0.15 a minute for all interstate and intrastate calls from state prison facilities. We applaud these efforts and seek comment below on what more the Commission and states can do to enact comprehensive ICS reform.

III. Discussion

19. In this Second Further Notice, we take the following steps to reform and modernize interstate and intrastate ICS regulations while ensuring adequate security measures for correctional facilities. First, we seek comment on eliminating all site commission payments on both interstate and intrastate ICS to fulfill the Commission's statutory obligations to promote competition and ensure just and reasonable rates and fair compensation. We also seek comment on whether facilities incur costs in the provision of ICS and, if so, how facilities should recover these costs, as well as appropriate transition periods for reform to allow correctional facilities time to adjust. We seek comment on adopting intrastate and interstate rate caps. We seek comment on reforming ancillary fees including adopting ancillary fee rate caps, and prohibiting certain ancillary charges. We also seek comment on alternative ways to promote competition in the ICS market. We seek comment on whether we should periodically review the ongoing impact of ICS rate reforms. Finally, we seek further comment on issues related to enforcement, disability access, advanced communications in the correctional setting, and the cost/benefit analysis of all of the proposals herein.

A. Payments to Correctional Facilities

20. The record, including data from the 2014 ICS Workshop and the Mandatory Data Collection, makes clear that the *Order*'s interim rate caps have significantly lowered the expense of interstate ICS calls to end users. On the positive side, the interim interstate rate caps have resulted in increased call volumes, evidence that unreasonable rates were discouraging communications and that reasonable rates foster communications between inmates and their families and friends. Yet failures in the ICS market continue. Interstate reform in some cases has been met by increased intrastate ICS rates and has not discouraged other practices that also increase the costs of ICS to consumers, such as excessive ancillary charges and an increase in the use of single call services. The pressure to pay site commissions that exceed the direct and reasonable costs incurred by the correctional facility in connection with the provision of ICS continues to disrupt and even invert the competitive dynamics of the industry. These and other market failures demonstrate that the interstate-only reforms adopted in the *Order,* while an important first step, did not completely address the problems in the ICS marketplace. This highlights the need for more-comprehensive reform of the ICS industry to address both interstate and intrastate ICS.

1. Restrictions on Payments to Correctional Facilities

21. In this section, we seek comment on prohibiting site commissions as a category, including all payments, whether in-kind payments, exchanges, allowances, or other fees. The record is clear that site commissions are the primary reason ICS rates are unjust and unreasonable and ICS compensation is unfair, and that such payments have continued to increase since our *Order.* Moreover, where states have eliminated site commissions, rates have fallen dramatically. We therefore predict that prohibiting such payments will enable the market to perform properly and encourage selection of ICS providers based on price, technology and services rather than on the highest site commission payment. Although we seek comment on prohibiting site commissions as a category, we seek comment on whether correctional institutions incur any costs in the provision of ICS and, if so, how to enable the facilities to recover such costs. We also seek comment on how best to proceed if a state has already prohibited site commission payments.

22. As part of its reform of unreasonable and unjust interstate ICS rates in the *Inmate Calling Report and Order and FNPRM,* the Commission addressed site commissions and concluded that they were an apportionment of profits between service providers and correctional facilities and were not, in and of themselves, a cost of ICS. The payment of site commissions distorts the ICS marketplace by creating ''reverse competition'' in which the financial interests of the entity making the buying decision (the correctional institution) are aligned with the seller (the ICS provider) and not the consumer (the incarcerated person or a member of his or her family).

23. This ''reverse competition'' is reflected in data in the record. Aggregated data from the Mandatory Data Collection from 14 ICS providers show that over $460 million in site commission payments were paid to facilities in 2013. This means that ICS users and their families, friends and lawyers spent over $460 million to pay for programs ranging from inmate welfare to roads to correctional facilities' staff salaries to the state or county's general budget. These are pass-through payments from the provider to the facility, absent which, rates would be lower. Moreover, the magnitude of payments is significantly higher than previous estimates in the record. For example, using publicly available data in 2012, the Human Rights Defense Center (HRDC) estimated ICS providers paid over $123 million in site commissions to correctional facilities. To put the number in context, however, the record and data from the Mandatory Data Collection suggest that these payments represented just 0.3 percent of prison facilities total budgets in 2012. Similarly, one ICS provider estimated

that site commission payments represented 0.4 percent of total prison/jail operating budgets in 2013. What appears to be of limited relative importance to the combined budgets of correctional facilities has potentially life-altering impacts on prisoners and their families.

24. Despite their limited overall budget impact, site commission payments are the chief criterion many correctional institutions use to select the ICS provider for their facilities and are thus the main cause of the dysfunction of the ICS marketplace. The demand for site commission payments generates pressure on ICS providers to raise rates and assess additional ancillary charges, which are typically not subject to site commissions. The existing contract proposal process (RFP, or request for proposal) often focuses the competition between bidding ICS providers on who can pay higher site commissions to correctional institutions instead of creating incentives for ICS providers to provide the lowest rates to consumers.

25. The Alabama PSC articulated an alternative perspective on the cause of increased site commissions, stating that ''the proliferation of excessive ancillary fees, not call rates, is the most significant contributor toward escalating site commission offerings.'' It further asserted that ''to effectively constrain excessive site commissions, it is essential to first address the excessive revenue sources [from ancillary fees].'' In this Second Further Notice we seek comment on proposals to address both site commissions and ancillary fees. We also seek comment on the Alabama PSC's perspective on the cause of increases in site commissions.

26. At the time the Commission adopted the *Inmate Calling Report and Order and FNPRM,* the highest commission amount in the record was 88 percent. Since the *Order,* despite the Commission's decision to not permit site commission payments to be included in interstate rates, the record indicates that site commissions have continued to increase, with recent contracts including site commission payments as high as 96 percent of gross revenues. Moreover, there is evidence that site commission payments on intrastate ICS revenue, which were not addressed by the *Order,* have increased. Absent further action, we are concerned that the market will continue to fail to promote competition and ensure rates are just, reasonable and ensure fair compensation consistent with the dictates of the Communications Act. Indeed, several commenters urge the Commission to adopt an approach that ''will lead to lower, market-based rates.'' Securus has suggested that if the Commission does anything short of completely banning site commission payments, it will allow gaming.

27. We seek comment on prohibiting all site commission payments for interstate and intrastate ICS to enable market-based dynamics to ensure just and reasonable ICS rates and fair ICS compensation. Eliminating the competition-distorting role site commissions play in the marketplace should enable correctional institutions to prioritize lower rates and higher service quality as decisional criteria in their RFPs, thereby giving ICS providers an incentive to offer the lowest end-user rates. Indeed, when states such as Missouri, New York and New Mexico eliminated site commission payments, ICS rates decreased significantly. We therefore seek comment on such an approach and on whether it will foster a competitive market that will ensure just and reasonable rates and fair compensation for ICS while minimizing regulatory burdens on ICS providers and the Commission. We also seek comment below on whether the Commission should undertake periodic review to verify this.

28. We seek comment on a two-year transition away from site commissions to avoid flash cuts and permit correctional institutions time to adjust. In addition, we seek comment on whether correctional facilities incur costs for provisioning ICS. We request data that demonstrate the costs that facilities bear that are directly related to the provision of ICS. We seek comment on the magnitude of these costs and how to enable facilities to recover such demonstrated costs in a manner that does not disrupt a market-based approach to lowering rates for end users of ICS.

2. Legal Authority

29. We seek comment on the Commission's legal authority to restrict the payment of site commissions in the ICS context pursuant to sections 276 and 201(b) of the Act. We begin with a review of the authority accorded the Commission under section 276. In relevant part, section 276(b)(1) states:

> In order to promote competition among payphone service providers and promote the widespread deployment of payphone services to the benefit of the general public, within 9 months after the date of enactment of the Telecommunications Act of 1996, the Commission shall take all actions necessary (including any reconsideration) to prescribe regulations that—
>
> (A) establish a per call compensation plan to ensure that all payphone service providers are fairly compensated for each and every completed intrastate and interstate call using their payphone. . . .

30. As discussed herein, the Commission has previously concluded that site commission payments are a significant cause of ever increasing rates. This fact was recently underscored by the Joint Provider Reform Proposal, which stated that the rate caps they propose ''are feasible for the parties only if implemented in conjunction with corresponding reductions in site commission payments.'' We seek comment on the assertion that absent reform, achieving the statutory mandate of just and reasonable ICS rates and fair ICS compensation would be difficult, if not impossible, to achieve. At the same time, we are mindful that ICS providers should receive ''fair'' but not excessive compensation, and seek comment on implementation and transition below to ensure that this occurs. We therefore seek comment on whether the payment of site commissions would be an appropriate object of regulation under this statutory provision. Would a prohibition on site commission payments ensure ''fair compensation'' as that term is used in section 276? While the Commission has previously found the phrase ''fairly compensated'' to be ambiguous, and acknowledged that a range of compensation rates could be considered fair, it has treated the concept of fairness as encompassing both the compensation received by ICS providers and the cost of the call paid by the end user. As the record continues to show that the payment of site commissions causes ICS rates to be set at excessive levels, could the Commission under section 276 find that site commissions result in unfair compensation and therefore should be prohibited or otherwise restricted?

31. We seek comment on our prediction that a prohibition on the payment of site commissions would foster a more competitive marketplace for the provision of ICS. If site commissions hinder and distort competition among ICS providers, hinder the widespread deployment of payphone services, or both, would that support the Commission's exercise of section 276 authority ''to prescribe regulations'' to ensure that ICS providers are ''fairly compensated''? If so, would the statutory duty to ensure fair compensation encompass an outright ban on the payment of site commissions by ICS providers? We note, for example, that if a correctional institution were to self-provision ICS and seek to charge rates that include an amount that would be deemed a site

commission as part of its profits, above and beyond a normal return, such conduct could be directly addressed by Commission regulation of ICS rates to limit rates to a level that ensures fair compensation, but no more. Does this approach support the view that Commission regulation directly targeting site commissions likewise can be justified to the extent providers ensure that ICS rates provide no more than fair compensation?

32. If, as the record currently shows, the payment of site commissions leads to ICS rates that are set at unreasonably high, even exorbitant, levels, then, as has occurred in states that have eliminated site commissions, we predict that a prohibition on making these payments would lead to significantly lower ICS rates. We seek comment on the reasonableness of this presumption and whether there are criteria other than site commissions that might discourage correctional institutions from prioritizing lower rates and better service quality in their RFPs. If the elimination of site commissions does lead to lower rates, we seek comment on whether lower ICS rates would lead to greater ICS usage. How should we interpret the word ''deployment'' in this context? For instance, is ''deployment'' limited to installation of new physical infrastructure that would enable the provision of ICS, or can ''deployment'' reasonably be construed to include new incentives or opportunities for end users to access existing payphone services? Similarly, can ''payphone service''—which section 276 defines to include ''any ancillary services''—reasonably be construed to include new features that might be offered to accommodate greater demand? We seek comment on this analysis.

33. We seek comment on any other relevant language in section 276 that may bear upon our authority to prohibit site commissions. For instance, what is the relevance of section 276(b)(1)(A)'s requirement that regulations adopted by the Commission ensure that payphone service providers are compensated ''per call'' and for ''each and every completed intrastate and interstate call''? More generally, are there alternative interpretations or theories for implementing section 276 that counsel for or against particular approaches to addressing site commission payments?

34. We seek comment on the proposal that site commission payments undermine the achievement of section 276's goals in the ICS context, even though the Commission previously has permitted location rents in the context of public payphones. For example, as to public payphones, the Commission found that ''[p]ayphones in many locations are likely to face a sufficient level of competition from payphones at nearby locations to ensure that prices are at the competitive level,'' and thus ''[a]s a result, we believe that payphones at such locations are unlikely to need additional scrutiny.'' The Commission recognized, by contrast, that there could be ''locations where . . . no 'off premises' payphone serves as an adequate substitute for an 'on premises' payphone.'' As the Commission observed:

> In such locations, the location provider can contract exclusively with one PSP [payphone service provider] to establish that PSP as the monopoly provider of payphone service. Absent any regulation, this could allow the PSP to charge supra-competitive prices. The location provider would share in the resulting ''location rents'' through commissions paid by the PSPs. To the extent that market forces cannot ensure competitive prices at such locations, continued regulation may be necessary.

35. We seek comment on whether market conditions for ICS differ sufficiently from those the Commission previously found in the case of public payphones as to warrant different treatment under section 276. Are ICS providers inherently ''monopoly providers of payphone service'' and therefore able ''to charge supra-competitive prices?'' Do inmates have access to competing alternatives? One way to mitigate this problem would be to require correctional institutions to enter into service contracts with multiple ICS providers instead of awarding a monopoly to a single provider, as the Wright Petitioners initially suggested. However, the record suggests that requiring multiple providers at correctional institutions, and thereby enabling competition, could present significant practical challenges and potentially could increase costs and therefore drive up rates. Further, it is unclear whether allowing multiple providers at correctional institutions would substantially lower ICS costs to consumers if facilities were still able to receive site commission payments. We seek comment on these views, and whether action on site commissions thus can be reconciled with Commission precedent under section 276 for public payphones, or if action to prohibit or restrict site commissions for ICS locations would require the Commission to change course in any respect.

36. We also seek comment on any other sources of Commission authority to regulate site commissions. For example, section 201(b) of the Act requires all charges and practices ''for and in connection with'' an interstate common carrier service to be ''just and reasonable.'' We seek comment on whether section 201(b), independent of any authority under section 276, gives us jurisdiction to prohibit the payment of site commissions for interstate ICS. Is the payment of site commissions a ''practice'' under section 201(b)? Conversely, could it be viewed as a ''rate,'' or component of a ''rate,'' under section 201(b)? Under either alternative, is the payment of site commissions ''for and in connection with'' interstate ICS? To what extent would a prohibition of site commissions under section 201(b) differ from a prohibition under section 276? Are there circumstances under which section 201(b) would support the regulation of site commissions in connection with intrastate, as well as interstate, ICS? For example, would declining to prohibit or restrict site commissions in connection with intrastate ICS undermine the Commission's ability to ensure lawful interstate ICS rates? Do other statutory provisions inform how the Commission can or should approach the issue of site commissions in the ICS context? The possible reforms that we seek comment on would apply to site commissions on both interstate and intrastate ICS traffic. In what ways would the Commission's legal basis for its actions differ based on the jurisdiction of the traffic under particular legal theories? In addition to regulating ICS providers' payment of site commissions, does section 276 or other Commission authority enable us to regulate the conduct of correctional institutions or other third parties if they seek to induce ICS providers to make such payments? If so, what is that authority?

3. Possible Reforms to Site Commissions

37. We seek comment on prohibiting site commission payments for all ICS as part of comprehensive reform and whether transitioning away from site commission payments is essential to achieving the statutory requirements of just and reasonable ICS rates and fair ICS compensation. We seek comment on a definition of site commission payments that are subject to any prohibition or restriction to include ''payments in money or services from ICS providers to correctional facilities or associated government agencies, regardless of the terminology the parties to the agreement use to describe them.'' We seek comment on interpreting this language to include any products or any other thing of value such as, for example, so-called ''contract administration'' fees. This is consistent with the approach in the *Order* where

the Commission noted that it would treat in-kind payments as site commissions.

38. The Joint Provider Reform Proposal supports the elimination of site commissions and proposes a similar definition of impermissible site commission payments to include a comprehensive range of ''in-kind payments, exchanges, technology allowances, administrative fees, or the like.'' It proposes that ''the Commission define as impermissible: Any payment, service, or product offered to, or solicited by an agency (or its agent) that is not directly related to, or integrated with, the provision of communications service in a correctional facility.'' We seek comment on these definitions and on any other ways to define ICS provider payments to correctional institutions that would be subject to any regulation discussed herein. We also seek comment on whether we should prohibit gifts or charitable contributions from ICS providers to correctional facilities to ensure they are not used to undermine a potential site commission prohibition. In an analogous context, the Commission included in its E-rate program rules a prohibition on gifts by service providers to schools or libraries to ensure that such gifts do not ''circumvent competitive bidding and other E-rate program rules.'' Additionally, we seek comment on whether any certification required of ICS providers should include a certification of compliance with any prohibition on site commissions and gifts the Commission may impose.

39. *Costs Incurred by Correctional Facilities.* Although we seek comment on eliminating site commissions as a category, the Commission acknowledged in the *Order* that some portion of payments to correctional facilities ''may, in certain circumstances, reimburse correctional facilities for . . . costs,'' such as security costs, that the Commission would likely consider reasonably and directly related to the provision of ICS. Consistent with the *Order,* we seek comment on whether correctional institutions incur any costs in the provision of ICS and, if so, how to quantify them and how the facilities should recover such costs. We seek comment on the idea that any recovery by facilities for costs reasonably and directly related to making ICS available be built into any per-minute ICS rate caps set by the Commission.

40. We seek comment on any filings in the record attempting to demonstrate ''legitimate costs incurred by correctional facilities . . . related to the provision of inmate calling services.'' The Joint Provider Reform Proposal states that ''[t]he parties recognize . . . that correctional facilities may incur administrative and security costs to provide inmates with access to ICS,'' referencing them as ''admin-support payments.'' Yet, the participating providers ''have not reached agreement as to what amount or what percentage (if any) should be required, or how such admin-support payments can accurately be measured.'' Some parties suggest that costs to facilities may include monitoring calls, submitting trouble tickets on equipment, handling billing disputes that inmates may have with the provider, and infrastructure and security costs. Praeses asserts that ''correctional facilities incur real costs to enable inmate calling'' and lists a number of functions they assert are related to such costs. However, other parties question whether the facilities incur any additional costs for the provision of ICS. Also, Securus notes that correctional facilities benefit significantly from having ICS in terms of reduced recidivism, solving and preventing crimes and inmate control and satisfaction suggesting that any costs are far outweighed by the benefits. Should the Commission be concerned that prohibiting or restricting site commission payments or prohibiting rates that include recovery of site commissions will lead correctional facilities to stop allowing inmates access to ICS altogether, or else to restrict inmates' access to ICS? We seek comment on whether correctional institutions in states that have prohibited site commissions bear any costs and, if so, whether such costs are recovered through ICS rates or are recovered through the general budget of the correctional institution.

41. We note that because the Mandatory Data Collection applied to ICS providers, not correctional institutions, the costs submitted by the providers do not include any costs that may be incurred by facilities. We seek comment on the actual costs, if any, incurred by correctional facilities in providing ICS, the amounts associated with these costs, and the appropriate vehicle for enabling facilities to recover such costs. Is an allocation of a guard's time for walking a prisoner to an ICS facility necessary and appropriate to include in ICS costs? Do facilities monitor calls for security purposes or is such monitoring done by ICS providers? If facilities monitor calls, should such costs be considered a cost recoverable through ICS rates? The Allegany County, NY Sheriff asserted that his facility ''does experience real costs in administering these services,'' but did not quantify or otherwise provide a context for understanding the relative magnitude of these costs as compared to the county's correctional budget.

42. The record is mixed on whether, and if so, how much facilities spend on ICS. For example, GTL provides research that suggests significant variations in how facilities apportion costs. For example, one department of correction that GTL serves allocates 42 full time employees to the provision of security for ICS, whereas a second, similarly sized, department of correction allocates only 0.5 full time employees to the provision of security for ICS. GTL estimates prisons' ICS-related costs at $0.005 per minute of use and jails' costs at $0.016 per minute of use, or 3.4 percent of total ICS revenue at prisons and 7.6 percent in jails. In contrast, CenturyLink asserts that to ''monitor just ten percent of the calls placed by inmates at either a prison or a jail would cost the facility 5.28 cents per minute applied to all calls placed by inmates at the facility.'' We seek comment on these estimated costs, particularly on why they vary so significantly, and the underlying assumptions, i.e., staffing costs and time commitments. For example, CenturyLink provides a list of ''administrative and security functions'' that correctional facilities commonly perform,'' such as ''responding to other law enforcement requests for records/recordings,'' validating attorney or other privileged numbers, ''blocking/unblocking numbers blocked for security issues,'' and ''administration of debit purchase.'' We seek comment on this list of functions and whether, in commenters' experiences, it accurately represents costs that correctional facilities incur in the provision of ICS. Other comments contend that ICS facilities do not incur costs in the provision of ICS. For example, is it appropriate for any portion of a salary of a full-time guard to be considered a cost of ICS?

43. To the extent the record indicates that facilities incur costs related to the provision of ICS, we seek comment on allowing cost recovery through a per-minute rate cap included in any rate cap adopted by the Commission, or some other approach. The per-minute approach presumes that facilities' costs vary with usage. We seek comment on the variable or fixed nature of correctional institutions' costs. GTL estimates prisons' ICS-related costs at $0.005 per minute of use and jails' costs at $0.016 per minute of use. We seek comment on whether a per-minute amount between $0.005 and $0.016 or at

some other per minute amount would ensure that correctional facilities recover their costs. Would allowing cost recovery based on a per-minute amount give correctional facilities an incentive to increase ICS usage? What would be the policy advantages or disadvantages of such an approach? Would correctional facilities be likely to select ICS providers with lower rates and fees, so as to increase usage and, depending on the elasticity of demand, thereby increase cost recovery to the facilities? We seek comment on whether any such cap should be reevaluated and adjusted as minutes of use (MOU) change.

44. We seek comment on using a per-minute approach over one that would set such payments at a capped percentage of ICS revenues. This approach would promote simplicity and deter possible improper incentives tied to a percentage of revenues approach, as occurs today. If, however, we used a percentage-based approach, we seek comment on the appropriate level of any recovery percentage. GTL estimates prisons' ICS-related costs at 3.4 percent of total ICS revenue and jails' costs at 7.6 percent. We seek comment on whether a percent of gross revenues between 3.4 percent and 7.6 percent or some other percent amount would ensure correctional facilities recover their costs. Would basing cost recovery on a percentage of ICS revenues encourage gaming and provide no or less incentive to facilities to lower ICS rates? For example, would basing cost recovery amounts on a percentage of revenues give ICS providers incentives to maintain rates at the highest allowable level in order to maximize site commission revenues? Will correctional facilities structure their RFPs so as to require such an outcome? We seek comment below on a transition period to achieve any cost recovery level. Praeses suggests that the Commission should consider developing ''a safe harbor payment level in addition to a payment cap—in much the same way that the Commission regulated interstate ICS rates in the ICS Report and *Order* in light of the varying ICS costs borne by ICS providers with respect to the different types of correctional facilities served.'' We seek comment on these and any other alternative regulations that could govern the relationship between any restriction on site commissions and ICS rate regulations.

45. To ensure our reforms produce just and reasonable rates and fair compensation, we seek comment on whether state statutes or regulations that require any site commission payment, as we sought comment on defining here, are inconsistent with the possible regulation herein and would therefore be preempted, pursuant to section 276(c) as discussed below. What criteria should the Commission use to determine which state actions are consistent? For example, should state actions to eliminate or restrict site commissions be considered consistent with any reforms that the Commission adopts? Should such an approach also preempt state statutes that only mandate how site commissions are to be used, but not require them in the first instance? Or would such statutes simply be rendered moot to the extent that correctional institutions elect not to seek, or ICS providers elect not to pay, site commissions in those states?

46. We also seek comment on possible state roles to address the issues discussed above. Are there circumstances where states might be better positioned to engage in oversight? Would states be limited to oversight in the context of intrastate ICS or could they also play some role in the context of interstate ICS? If so, what might that role be? Finally, we seek comment on setting interstate and intrastate ICS rates at levels that do not include the recovery of site commission payments instead of prohibiting site commission payments directly. If the Commission determines that it does not have authority over site commission payments, does such an approach still allow for just and reasonable ICS rates as well as fair compensation? Would such an approach help satisfy the goals, provided in section 276 of the Act, of promoting competition and widespread deployment of payphone services?

B. Interstate and Intrastate ICS Rate Reform

47. A goal of ICS reform is to move to a market-based solution to reduce rates. While we continue to see the benefits of a the approach adopted in the *Order* last year, now that we are seeking comment on comprehensively reforming all aspects of ICS (including intrastate rates and site commissions) this allows the Commission to ask about a more market-based approach to promoting competition and just and reasonable rates and to ensure fair compensation. Given the high rates, excessive compensation and market failure we see today, we seek comment on adopting permanent rate caps to ensure that ICS rates are just and reasonable. These rate caps will serve as a backstop to the market-based solution described above. We seek comment on how to set those rate caps. Specifically, we seek comment below on the data submitted by ICS providers pursuant to the Mandatory Data Collection. We also seek comment on the proposals for rate reform filed in the record. In addition, we seek comment on prohibiting per-connection or per-call charges. Should any such expenses be collected through a per-minute rate? We seek comment on the best ways to address flat-rate charges for ICS.

48. We seek comment on adopting permanent rate caps for interstate and intrastate debit/prepaid and collect ICS calls. In the *Order,* the Commission adopted a requirement that rates be cost-based. At that time, because reform was limited to interstate rates, market forces alone would not bring all rates down to just and reasonable levels because intrastate rates, ancillary charges and site commission payments on intrastate rates would still thwart market forces. While we continue to see the benefits of a cost-based approach as adopted in the *Order* last year, the Commission prefers to allow market forces to ensure that rates are just and reasonable. Now that we seek comment on comprehensively reforming all aspects of ICS, including intrastate rates, will the elimination of site commissions facilitate the market moving to just and reasonable rates? We also seek comment on adopting permanent rate caps to ensure that ICS rates are just and reasonable and ICS compensation is fair, particularly while we transition away from site commissions. We ask about the advantages and disadvantages of this approach as compared to setting safe harbors or simply requiring cost-based rates. We seek comment above on a possible cost recovery amount for correctional facilities and seek comment on including an amount for correctional facility cost recovery in any rate caps ultimately adopted by the Commission.

49. *Data Analysis.* We seek comment on the data filed by the 14 ICS providers in response to the Mandatory Data Collection. The data filed by ICS providers include cost, site commission and ancillary services data, which are informative and useful, and we take this opportunity to remind all ICS providers of the filing requirement. These data include the cost of the full spectrum of safety and security features, including verification, monitoring and other advanced security capabilities that ensure that correctional facilities have the security necessary for the provision of ICS. We generally seek comment on the data and invite parties to analyze the data and submit any analysis consistent with the terms of the *Protective Order.* We also invite parties to submit concerns or alternative proposals for the Commission to consider as it evaluates further reforms. Throughout this section

we use 2012 and 2013 actual data filed by the responding ICS providers.

50. While the data are useful to the Commission's evaluation of further ICS reforms, we seek comment on some apparent inconsistencies and anomalies. For example, differing cost allocations by providers were particularly notable and could affect the consistency and reliability of the data as reported. The Wright Petitioners noted several anomalies based on their analysis of the data, including the fact that ''[t]he average cost per minute of use is substantially less than the interim Interstate ICS hard rate caps adopted in August 2013; [t]he ICS providers inconsistently allocated their costs among the four cost categories (Telecom, Equipment, Security, Other); [t]he ICS providers used different methodologies to allocate costs to facilities and payment methods.'' We seek comment on these apparent inconsistencies and how the data may be analyzed to make an allowance for such variances.

51. A large proportion of costs reported by ICS providers are common costs, which is consistent with the fact that ICS providers typically use centralized calling platforms to process calls from the different facilities they serve. The Commission's Mandatory Data Collection did not dictate a particular methodology for allocating common costs—and, indeed, doing so could have greatly increased the administrative burden of providing the data. As a result, the providers took varied and often inconsistent approaches to allocating common costs among types of facilities and types of services. Given the preponderance of common costs in ICS providers' data submissions, analysis of the data is particularly sensitive to such varied and inconsistent common cost allocation methodologies.

52. We note that, as a whole, ICS providers allocated common costs among types of facilities and types of services differently as compared to the volumes of traffic those facilities and services experienced. Specifically, ICS providers that served both jails and prisons generally allocated a higher proportion of their common costs to jails than would otherwise be warranted given the minutes of use from those jails. Although the exact allocation varied by provider, on average about two thirds of common costs were allocated to jails, whereas only about half the reported total traffic volume originated from jails. The data evidence similar discrepancies between the allocation of common costs to types of service and the volume of traffic for those services. For example, ICS providers as a whole allocated about 16 percent of their common costs to collect calls, whereas collect calls represented only about eight percent of total traffic. It is not readily apparent why common costs (as opposed to direct costs) would not follow usage more closely. And the results of the data from these allocations show costs for jails that are higher than proposals for comprehensive reform that the providers themselves submitted, which raises concerns about the accuracy of their methodology and whether alternative allocation methods would more accurately represent costs.

53. One possible approach to addressing apparent inconsistencies in the providers' common cost allocation methodologies would be to use minutes of use for each provider as an alternative basis on which to allocate providers' common costs. Given the high proportion of common costs reported by the industry and the centralized nature of its networks, using minutes of use to allocate common costs would seem likely to reflect the providers' operational realities. We seek comment on whether employing a usage-based allocation of common costs would more closely reflect cost causation and provide more consistent and reliable data. We further seek comment on how these data should inform the rate cap levels for interstate and intrastate debit/prepaid and collect calls. The following table shows the costs per minute for jails and prisons when using three different methods to allocate common costs: As submitted by ICS providers, as reallocated using total minutes of use, and as reallocated using the providers' cost allocations between jails and prisons prior to reallocating those costs by minutes of use for each type of and facility.

TABLE ONE

Facility type	Common costs as allocated by providers		Common costs allocated by MOU (in cents)		Common costs allocated by facility type (in cents)	
	Average debit/prepaid cost	Average collect cost	Average debit/prepaid cost	Average collect cost	Average debit/prepaid cost	Average collect cost
Jails	15.8	48.7	14.8	21.9	18.1	26.3
Prisons	10.0	13.7	14.0	17.2	9.9	14.3
All	13.3	28.3	14.5	19.2	N/A	N/A

54. We seek comment on the two reallocation methodologies in Table One, both of which use minutes of use in different ways as a means of reallocating common costs in manner tied more closely to usage. We initially examine and seek comment on the reallocation based on total minutes of use. This method uses the ratio of total industry minutes of use for jails to total minutes of use for all facilities to reallocate all common costs among facility and service types. Minutes of use for jails represent about 53 percent of all minutes of use, resulting in an allocation of about 53 percent of common costs to jails instead of the average of approximately 68 percent allocated to jails in the data as reported by providers. The results of this reallocation methodology are more consistent with provider proposals in the record, both from 2008 and more recently. For purposes of comparison, the 2008 ICS provider proposal reported costs of $0.164 per minute for debit calls and $0.236 per minute for collect calls, whereas the providers' data reported costs of $0.133 per minute for debit and prepaid and $0.283 per minute for collect. Similarly, the Joint Provider Reform Proposal recommends a single per-minute rate cap of $0.20 for debit and prepaid and $0.24 for collect calling. CenturyLink's proposal advocates unified rate caps at the current interstate caps ($0.21 for debit and prepaid and $0.25 for collect). We seek comment on these apparent allocational discrepancies.

55. This alternative methodology would standardize common cost allocations among the five providers that serve a mix of jails and prisons. And the fact that providers that serve only jails have no prison minutes of use would ensure that their common costs would not be allocated to prisons. Does

this method more closely approximate the operational realities of the providers? Is it more effective in replicating cost causation in the industry? Does it have any disparate impacts on providers that only serve jails?

56. We also examine and seek comment on a potential reallocation of providers' common costs based on providers' allocation of common costs to facility types (jails or prisons). This method accepts each individual provider's allocation of common costs between jails and prisons and then allocates those costs among facility and service types based on total minutes of use for each type of facility. This method shifts fewer costs to prisons and results in higher costs for jails than the total minutes of use allocation due to the reliance on the 68 percent average allocation of common costs to jails by providers, as noted above. Is this method more appropriate because providers' initial allocations of common costs are more accurate? Alternatively, is this method's greater reliance on the accuracy of those allocations a potential vulnerability or flaw?

57. The data provided by ICS providers also allocated costs to different subsets of facilities based on size of facility. This allocation resulted in a wider range of per-minute costs with some apparent anomalies, such as per-minute costs for certain facility size groups being well above the range of rate cap proposals submitted by any ICS provider, including those that exclusively serve purportedly higher-cost facilities such as jails. The cost data generated by facility size groups also resulted in some anomalies that raised questions about whether smaller facilities have higher costs than larger ones, and vice versa, as some commenters have asserted in this proceeding. Given confidentiality of the data, we cannot disaggregate all data for jails and prisons by size but we note that while the data indicate that smaller jails are most costly and the largest jails are less costly to serve, the data did not show the same correlation between size and cost for prisons. This raises questions about whether assumptions about facility size determining cost are accurate. Even if size were the appropriate measure, would the administrative burden of using rates tiered by size and type of facility outweigh the benefits of multiple rate tiers? Can rate caps for different types of services and facilities provide sufficient flexibility to ensure fair compensation short of resorting to size-based tiers? Does the Commission need to adopt such a regulatory approach?

58. To the extent that particular facilities are more costly to serve than suggested by the rate cap proposals in the record, can the Commission more effectively ensure fair compensation and reduce administrative costs to providers by addressing such outliers through the use of the waiver process? We note that the Commission already granted a waiver of its interim rate caps to one ICS provider to address unique circumstances. Would using a waiver process be easier to manage than adopting and policing the multiple rate tiers the Commission would otherwise have to adopt?

59. We also seek comment on other alternative methods of analyzing the ICS providers' cost data. For example, would evaluating jail data separately from prison data be useful? We seek comment on any other methods of evaluating the data that commenters may want to propose that may prove useful to the Commission in its analysis of this data to ensure just and reasonable rates and fair, not excessive, compensation.

60. *Previous Data Submissions in the Record.* ICS providers have previously filed data in the record throughout this proceeding. In 2008, seven ICS providers filed a cost study based on proprietary cost data for certain correctional facilities with varying call cost and call volume characteristics. The study indicated that the per-call cost for debit calls was $0.16 per minute and $0.24 per minute for collect calls. In response to the *2012 ICS NPRM,* Securus filed data which showed, as discussed in the *Order,* ''an average per-minute cost for interstate calls from all facilities included in the report to be $0.12 per minute with commissions and $0.04 per minute without them.'' Pay Tel filed financial and operational data for its ICS operations. The non-confidential cost summary included in the filing reported actual and projected 2012–2015 average total costs for collect and debit per-minute calling of approximately $0.23 and $0.21, respectively (including the cost of an advanced security feature known as continuous voice biometric identification). Although CenturyLink did not file a cost study at that time, it did file summary cost information for its ICS operations. Specifically, CenturyLink reported that its per minute costs to serve state departments of corrections facilities (excluding site commission payments) averaged $0.116 and that its per-minute costs to serve county correctional facilities (excluding site commission payments) averaged $0.137. We seek comment on how to reconcile these data submissions with the data filed in response to the Mandatory Data Collection and the Commission's analysis of that data described above, and how these data should inform our selection of rate caps. We also seek comment on and updates to intrastate rate data currently in the record. And we seek updated comment on international ICS and the need for Commission reform focused on such services.

1. Proposals for a Unitary Rate

61. Throughout this proceeding interested parties have filed in support of the Commission adopting unitary ICS rate caps for all intrastate and interstate debit/prepaid and collect calls in all facilities. We seek comment here on those proposals.

62. *Joint Provider Reform Proposal.* The Joint Provider Reform Proposal supports a rate cap of $0.20 per minute for debit and prepaid interstate and intrastate calls, and a rate cap of $0.24 per minute for all interstate and intrastate collect calls exclusive of per-call or per-connection charges, exclusive of any facility cost recovery, and regardless of facility size. The providers that submitted this proposal assert that this ''simplified rate structure'' ''will make ICS charges more transparent for inmates and their friends and family,'' as well as ''easy for ICS providers and correctional facilities to implement quickly, and will simplify oversight and enforcement.''

63. Pay Tel and the Alabama PSC have raised concerns about the Joint Provider Reform Proposal for a unitary rate and urged the adoption of different rates for jails and prisons. For example, Pay Tel stated that the rate caps were ''excessively high for prisons.''

64. We generally seek comment on the rate caps proposed by the Joint Provider Reform Proposal. We seek comment on how our data analysis described above reconciles with the rate caps proposed by the providers. As noted above, average debit and prepaid costs are lower than $0.20 per minute. Should we adopt the Joint Provider Reform Proposal's rate caps because any adopted rate caps will serve as a backstop to ensure that rates are just and reasonable? Would these rates enable the Commission to include a per-minute cost recovery of $0.005 for correctional facilities' cost recovery? We also seek comment on how ICS providers' earlier data filings reconcile with the rate caps suggested in the Joint Provider Reform Proposal.

65. *Current Interim Rate Caps.* Some parties have supported making the interim rate caps permanent for all interstate and intrastate ICS calls.

CenturyLink asserts that it could ''support a unified cap approximately at the current interstate cap levels.'' NCIC asserts that collect ICS rates should be capped at $0.25 per minute and debit call rates at $0.21 per minute. We seek comment on these proposals in light of the data received in response to the Mandatory Data Collection.

66. *Wright Petitioners' Proposal.* The Wright Petitioners previously proposed a $0.07/minute rate cap for all interstate ICS. We sought comment on this proposal in the *FNPRM,* particularly as it related to distance insensitive rate proposals. ICS providers suggested that the rate may jeopardize ICS security. Other commenters suggested that the Commission should adopt a $0.07/minute rate cap for all ICS and that current rates in states like New Mexico ($0.043/minute) and New York ($0.048/minute) support this cap. We now seek comment on whether we should adopt this proposal. If the Commission were to adopt this proposal, would rate caps at this level preclude ICS providers from paying site commissions and therefore negate the need for the Commission to regulate site commission payments as discussed above? What level of rate cap do commenters believe would change what providers are able to offer correctional facilities? Do the data from the Mandatory Data Collection support this rate cap? What are the considerations associated with such an approach?

2. Tiered Rate Caps

67. While we see certain benefits to a single set of rate caps such as administrative ease and avoidance of potential loopholes, some commenters recommend rates tied to the size or type of facility. In the *FNPRM* the Commission sought comment on the adoption of, and benefits of, tiered rates based on a facility's volume of minutes, type (i.e., jail versus prison) or size. Responses centered on the distinction between jails and prisons, with some commenters advocating for different ICS rate tiers for jails and prisons. These same commenters also point out that the differences between jails and prisons are not absolute, and acknowledge that some prisons ''are more costly to serve than jails and the range of costs of serving jails and prisons is very wide.'' The record indicates that jail administrators support a tiered rate instead of a flat rate because jails may face different costs than prisons as a result of their smaller size, higher turnover rate, and relative inability to take advantage of economies of scale. How do the data collected and reported herein impact our evaluation of these claims?

68. *Pay Tel Proposal.* In its proposal Pay Tel recommends separate rates for jails and prisons. Pay Tel proposes an $0.08 per minute rate for all prisons regardless of population. Pay Tel also estimated a $0.067 per minute average rate for the eight state prison systems that barred site commissions. Pay Tel suggests a rate of $0.26 per minute for jails with 1–349 average daily population [ADP], a $0.22 per minute rate for jails with 350 plus ADP, and a $0.08 per minute rate for all prisons regardless of size. We seek comment on these proposed rate caps.

69. Alabama recently adopted ICS rates tied to facility type. For example, the Alabama PSC has adopted per-minute rates of $0.30, decreasing to $0.25 over two years, for jails and $0.25, decreasing to $0.21 over two years, for prisons. We seek comment on this approach.

70. Commenters suggest that rates tied to the type or size of facility would open loopholes in ICS reform and allow for gaming. Is this accurate? Recently, CenturyLink said it ''does not support complex or tiered rate caps.'' Other commenters contend that an insufficient record exists from which to develop rate tiers, and point to evidence that many jails house long-term inmates, which may indicate that costly account set-up fees are less of an issue than suggested. Do the data received in response to the Mandatory Data Collection assuage the concern regarding the sufficiency of the record? The data also suggest that certain ICS providers reported a large proportion of the costs of ICS as common costs, rather than direct or facility-specific costs. Does this further call into question the cost allocation methods used by providers in their data submissions to allocate common and direct costs? Or does it suggest that ICS providers did not use uniform standards to distinguish between direct and common costs? We seek updated comment on interested parties' opinions on tiered rates for different types of facilities. Specifically, if the Commission adopts a market-based approach of addressing site commission payments and allowing competition to drive rates closer to cost, should we consider rate tiers, or should we instead adopt common rate caps for all correctional institutions to accommodate any differences between jails and prisons? Would the adoption of tiered rates help promote competition among ICS providers and promote the widespread deployment of ICS—a form of payphone service—consistent with the goals of section 276? For example, would a lower rate cap for ICS in prison facilities promote additional usage, a potential means of promoting widespread deployment of payphone ICS service?

71. The Commission seeks comment above on prohibiting site commissions to address the primary cause of the ICS market failure. If the Commission does not prohibit site commissions should we focus more on rates tied to facility size or type? If the Commission were to set tiered rates, we seek comment on defining a jail facility as a correctional facility operated by a political subdivision of a state or its agent and defining a prison facility as a state-run or federally-run correctional facility. How would differences in tiered rate caps be administered? We seek comment on a simpler approach. Would a variety of rate caps cause confusion? We also seek comment on the administrability of cost on 4ICS providers on an approach that varies by size and type of facility. CenturyLink urges the Commission to exclude from ICS rate reform certain types of facilities that it considers high-cost, such as juvenile detention centers and secure mental health facilities. Do other commenters agree that these types of facilities are particularly high cost? If so, why? Are there other categories of facilities that the Commission should consider exempting because they are high cost? Would doing so be in keeping with our statutory mandate? How should the Commission regulate the provision of ICS at such facilities? Should it exempt such facilities from ICS rate reform? We seek comment on the appropriate definitions for juvenile detention facilities and secure mental health facilities.

72. In the *FNPRM,* the Commission also sought comment on rate tiers based on facility size as measured by the average daily population of the facility. The Prison Policy Initiative suggested that the Commission could use the Census of Jail Facilities population data to capture facility size but could also use more recent data. Would following the Census numbers result in too few or too many tiers? We seek comment on what interested parties believe to be the appropriate inflection points, in terms of ICS providers' scalability of costs, with regard to possible tiered rates. Some states have recently adopted ICS rate tiering. We seek comment on the jail and prison rates adopted by the Alabama PSC or any other states.

3. Additional Considerations Related to ICS Rates

73. *Debit/Prepaid and Collect Calling.* In the Order the Commission treated

debit and prepaid ICS alike and collect ICS separately because ''[t]he record indicates that prepaid calling is generally less expensive than collect calling but can be about equal in rates to debit calling.'' Data from the Mandatory Data Collection suggest a difference in cost between collect ICS calling and debit/prepaid ICS calling. The data also show, however, that debit and prepaid ICS costs are very similar. Commenters have recommended higher rates for collect calls. The Alabama PSC adopted different rate caps for different types of service from prisons. Other commenters have opposed differentiated rate caps for different types of ICS. We seek comment on retaining this distinction and adopting a rate cap for debit and prepaid calls and a rate cap for collect calls. We also seek comment on the appropriate differential, if any, between the debit/prepaid cap and the collect cap.

74. *Per-Call or Per-Connection Charges.* Per-call or per-connection charges are one-time fees often charged to ICS users at call initiation. We seek comment on banning the imposition of per-call or per-connection charges. In the *Inmate Calling Report and Order and FNPRM* the Commission noted several problems with per-call or per-connection charges, including the level of some of the charges, their effect on the rate for short calls, and evidence of premature, non-security related call terminations, and the assessment of multiple per-call charges for what was, in effect, a single conversation. The Commission, recognizing that many different ways to address per-call charges exist, did not prohibit all per-call charges in the *Order* but sought comment in the *FNPRM.* In the *FNPRM* the Commission noted the flexibility it gave ICS providers to use a rate structure that included per call charges and sought further comment on the risks and benefits of allowing per call charges. Specifically, the Commission ''express[ed] serious concerns about such charges.'' Some commenters suggested that the Commission eliminate per-call charges and that doing so would be beneficial because it ''would lead to significant reductions in customer complaints regarding charges associated with dropped calls and in the amount of time providers are required to spend analyzing and resolving such complaints.'' Is there continuing evidence of premature, non-security related call terminations since the Commission adopted the *Order*? The per-minute rate caps proposed by Joint ICS Providers do not contemplate the continued charging of a per-call or per-connection fee.

75. We seek comment on our legal authority to ban the imposition of per-call or per-connection charges, for both interstate ICS calls and intrastate ICS calls. More specifically, we seek comment on whether such fees are part of the rate for ICS and therefore subject to the section 276 mandate to ensure fair compensation. Alternatively, should the Commission consider per-call or per-connection charges an ancillary service as discussed in section 276(d)? Are there instances in which the correctional facility or some other third party assesses a per-call or per-connection fee? If so, we seek comment on our authority to ban such charges. Would the elimination of per-call charges allow for just and reasonable interstate and intrastate ICS rates and fair compensation for providers? Would pure per-minute rate caps at an appropriate level or levels ensure fair compensation for ICS providers? Section 276 specifically requires us to ''establish a per call compensation plan.'' We seek comment on whether section 276 gives the Commission the legal authority to ban per-call compensation. We seek comment on whether we should also rely on our section 201 authority to ban per-call charges for interstate calls. The record has not shown significant per-call costs that could not reasonably be recovered using per-minute charges. With one exception, ICS providers have successfully implemented the interim per-minute rate caps for interstate ICS mandated by the *Order.* We seek comment below on transitions and whether rate caps should be effective 90 days after the effective date of a Commission order. If the Commission continues to allow per-call charges, should it nonetheless disallow an additional per-call charge when a call has been reinitiated within one or two minutes of having been mistakenly disconnected? If states have conducted ICS reform, we seek comment on whether we should review the effective rates for consistency with the Commission's regulations based on the calculation of the cost of a 15-minute ICS call. Are there other considerations relating to per-call charges in the ICS context that the Commission should consider?

76. *Flat-Rate Charges.* We seek comment on whether or not it is necessary to ban flat-rated charges for calls of a fixed duration to ensure rates are just and reasonable and fair. In the *Order* the Commission stated that ''a rate will be considered consistent with our rate cap for a 15-minute conversation if it does not exceed $3.75 for a 15-minute call using collect calling, or $3.15 for a 15-minute call using debit, prepaid, or prepaid collect calling.'' Rule 64.6030 mirrors this language and was intended to illustrate that a five-minute collect call would equal $1.25 and a five-minute debit or prepaid ICS call would equal $1.05, while a 30-minute collect call could equal no more than $7.50 and a 30-minute debit or prepaid ICS call could equal no more than $6.30. In the *FNPRM* the Commission sought comment on whether it should adopt an overall rate cap based on call duration, how such a rate cap might ensure that ICS rates are just, reasonable, and fair, and whether a per-minute cap is still necessary to ensure that shorter calls are reasonably priced. Commenters expressed concern that ''consumers who make shorter calls would necessarily be penalized'' and that ''there is no principled basis for capping the amount that can be charged for a call.'' The Public Service Commission of the District of Columbia discussed the benefits of its $1.75 per-call cap regardless of call length.

77. Subsequent to the *FNPRM* comment deadline, Securus sought additional guidance on whether the *Order* allows providers to use a flat-rated charge based on the interim rate caps for a 15-minute call regardless of call duration. We seek comment on this practice. Should we allow ICS providers to charge fixed call duration pricing for all interstate ICS usage regardless of call duration? Is this an appropriate interpretation and application of rule 64.6030 and the relevant discussion in the *Order*? We also seek comment on how we should address the use of flat-rate charges for ICS going forward and our legal authority to act on such charges. We seek comment on whether we should revise the existing rules to prohibit flat-rate charges or develop new rules prohibiting flat-rated charges. If not, how much flexibility should the Commission allow if flat-rate charges are permitted? How can we ensure that flat-rate charges allow for just and reasonable ICS rates to end users as well as fair compensation to ICS providers?

78. One commenter asserts that correctional facilities seek such flat-rated charges. Is this the case and, if so, why? What impact would allowing this level of flexibility have on the effective per-minute rates end users pay? If the Commission adopted a lesser degree of flexibility, how would it work? Should such a flat rate be used only for calls 15 minutes in length? Will flat-rated charges, at the rate caps discussed above, for a 15-minute call duration

allow for just and reasonable ICS rates and fair compensation? In the *Order,* the Commission found that the record supported 15-minute average call duration. Data from the Mandatory Data Collection show that the average call length reported by respondents was below 13 minutes in 2013. Is 15 minutes still a useful average call duration for purposes of discussing flat-rate charges? If not, what would be an appropriate average call duration?

79. *Waivers.* The *Order* made clear that the Commission's standard waiver process applies to ICS, specifically, that ICS providers seeking a waiver of the interim rules must demonstrate good cause. The Commission delegated to the Bureau the authority to seek additional information necessary for evaluating waivers. Since release of the *Order,* the Bureau has processed three waiver requests. CenturyLink suggests that the Commission ''invite waivers where new rules conflict with state statutes, or where they would force ICS providers to offer service at a loss.'' The ICS providers that submitted the Joint Provider Reform Proposal suggest that the Commission ''permit an ICS provider to seek a waiver of the rate cap for a particular correctional facility if the ICS provider can demonstrate that the proposed rate cap does not allow the ICS provider to economically serve the correctional facility. However, such waivers should be permissible only on a facility-by-facility basis.'' We seek comment on these suggestions. Specifically, is such action necessary if the Commission preempts inconsistent state regulations pursuant to section 276(c) of the Act? We seek comment on how the Commission would determine that rates are below-cost in a waiver proceeding and how any adopted regulations should address this issue. We further seek comment on what information would be important for providers to demonstrate when seeking a waiver in the ICS context. We also seek comment on whether exempting a provider's highest-cost facilities from the final, adopted regulations would be a suitable remedy to a waiver request. Conversely, would such an exemption encourage ICS providers to focus on particular facilities so as to arbitrage our rules?

C. Reforms to Ancillary Charges

1. Background

80. In addition to unreasonable rates, ICS providers typically assess a wide range of separate charges for services ancillary to the provision of ICS. These charges impose significant additional burdens on consumers and considerably inflate the effective price they pay for ICS. The record indicates that ancillary charges represent a significant proportion of the total expense of ICS to consumers. The Prison Policy Initiative estimated that ancillary charges represent 38 percent of all consumer payments for ICS. Others have suggested that this estimate may be low. Fees to open, fund, maintain, close, and refund an ICS account represent just a few of a variety of ancillary charges assessed by ICS providers. The sheer number of ancillary charges, their varying nomenclature, and the variability of the amounts charged cause considerable customer confusion, let alone consternation.

81. In the *Order,* the Commission ''question[ed] whether such charges are reasonable in and of themselves'' and noted that ''the levels of such charges do not appear to be cost-based.'' The Commission required that all interstate ancillary service charges be cost-based and reasonably and directly related to provision of ICS. The Commission concluded that it had the jurisdiction and authority to regulate ancillary service charges. The Commission also required ICS providers to file cost data about ancillary services as part of the Mandatory Data Collection, and in the *FNPRM* sought comment on additional steps the Commission could take to address ancillary service charges and ensure that they are cost-based. We now seek further comment on issues related to ICS ancillary charges.

82. Since the release of the *Order,* evidence indicates that ancillary charges have increased, suggesting that any reforms limited to ICS rates could be circumvented through increased and new ancillary charges. As the Commission stated in the *Order,* ICS reform and ensuring just and reasonable rates to end users ''could not be achieved if ancillary charges were not also controlled.'' Given that ancillary charges are typically shielded from site commission assessments in correctional institutions' contracts with providers, ICS providers appear to have an incentive to assess additional ancillary charges as an alternative source of revenue to compensate for lowered ICS rates or for increasingly high site commission payments. We seek comment on the extent to which the proliferation of ancillary charges may be a result of the market distorting effects of site commissions.

83. There is broad consensus in the record on the need for the Commission to reform ancillary charges. The Wright Petitioners and prisoner advocacy groups have recommended the regulation or elimination of ancillary charges. A number of ICS providers have made similar recommendations. For example, CenturyLink stated that ''the Commission should prohibit all or all but a very narrow class of ancillary fees. Ancillary fees are the chief source of consumer abuse and allow circumvention of rate caps.'' NCIC stated ''[a]lthough telecom companies don't normally welcome a regulation, we see the need for the FCC and state regulators to set a standard rate and fee structure.'' Pay Tel stated ''you ought to get rid of all of them except the fees where the consumer makes a choice.'' And Securus stated that it ''offered, however, to cease passing through several types of fees and to cap its fees for optional, convenient payment methods for a period of five years.''

84. *Mandatory Data Collection.* ICS providers submitted a significant amount of ancillary service cost and usage data in response to the Mandatory Data Collection. The ancillary services data provide some useful insight into the costs of ancillary services. For example, the data show that approximately 82 percent of total ancillary costs incurred by ICS providers pertain to the provision of bill processing services, particularly for the processing of credit and debit card transactions. Conversely, only about 10 percent of providers' ancillary costs pertain to ancillary services that are typically treated as normal utility overhead. Even so, the data have some limitations given providers' inconsistent approaches in assessing and labeling such fees, different allocation methodologies, and different ways of reporting those costs. The data, while mixed, also show that the per transaction cost of processing financial transactions point to the reasonable nature of the $3.00 caps for financial transaction processing fees set by the Alabama PSC. We seek comment on these general observations and on the ancillary charge data generally.

2. Legal Authority for Ancillary Charge Reform

85. In the *Order,* the Commission asserted jurisdiction over interstate ICS ancillary charges, citing as sources of authority sections 201(b) and 276 of the Act. Given section 276's mandate of fair compensation ''for each and every completed intrastate and interstate call,'' and its inclusion of ''inmate telephone service'' and ''any ancillary services'' in the definition of ''payphone service,'' we seek comment on whether section 276 gives the Commission authority to regulate both interstate and intrastate charges for ICS ancillary services. While the Commission has

previously adopted a definition of ancillary charges, we have not adopted a definition for ''ancillary services'' and therefore seek comment on such a definition. Additionally, given the absence of any qualifying statutory language to the contrary, we seek comment on whether section 276 gives the Commission jurisdiction over charges that are ancillary to ICS to the extent such services are considered IP-enabled services. Further, in the *Order* the Commission asserted in regard to ICS generally that ''[o]ur exercise of authority under sections 201 and 276 is further informed by the principles of Title I of the Act.''

86. We seek comment on whether this assertion also encompasses the Commission's regulation of services ancillary to the provision of ICS to the extent that ICS may be considered an IP-enabled service. Additionally, to the extent that ancillary charges are assessed in connection with ICS provided through wireless phones, we seek comment on whether sections 276 and 332(c) confer jurisdiction on the Commission to reform such fees. We also seek comment on assertions that charges for ancillary services are primarily related to billing and collection and therefore may not be considered to be communications services subject to Commission regulation. Finally, we seek comment on whether regulation by the Commission of ICS ancillary services should be treated as a default federal framework, with states encouraged to adopt additional reforms to the extent they are consistent with the Commission's regulations. Regarding the jurisdictional nature of ancillary charges, the Alabama PSC stated that ''any schedule of ancillary fees applies to both the interstate and intrastate jurisdictions.'' Are ancillary charges inherently dual jurisdictional in nature? We seek comment on this assertion and its impact on our legal authority to regulate such charges.

3. Discussion

a. Prohibition of Certain Ancillary Charges

87. The *FNPRM* sought comment on whether certain ancillary charges constituted unjust and unreasonable practices under section 201(b), or practices that would result in providers being unfairly compensated under section 276. We now seek comment on prohibiting separate charges for certain ancillary services that are basic requirements for consumers to gain access to ICS, and that are typically recovered through rates as part of normal utility overhead costs. We also seek comment on capping charges for certain other ancillary services such as payment processing for credit and debit card payments that enhance convenience for ICS consumers. We seek comment on whether this approach will promote the Commission's mandate of ensuring just and reasonable ICS rates and fair compensation for ICS providers, as well as promote competition and deployment in the ICS market.

88. The record, including the discussion at the Commission's 2014 ICS Workshop, supports the notion that the Commission should prohibit separate ancillary charges for services that represent normal utility overhead but allow other charges for services that represent an additional option or convenience for consumers. For example, the Alabama PSC workshop participant stated that its approach ''is first, establish a basic level of ICS service and what is included in that basic service at no additional charge to the customer. . . . Beyond that basic level, the Commission will consider fees.'' The Alabama PSC participant described its goal to be to ''[m]ake the rates a true reflection of cost for providing the service.'' Other commenters support making a similar distinction. For example, Pay Tel's President stated at the 2014 ICS Workshop ''what I characterize as ancillary fees are all these extra things that really should be incorporated into the cost of the call. . . . [T]he fees that should be separated are the ones that are driven by consumer choice.'' Securus similarly proposed ''not to have any mandatory fees and to have only fees for optional, convenience-related payment methods.'' The Minnesota Department of Commerce stated that if an ancillary charge applies ''to all ICS end-users at a facility, or cannot be avoided by a purchaser of ICS (e.g., in a situation in which a no-cost alternative is not offered), the ancillary charge or line-item fee should be incorporated in the per-minute rate, and should be subject to the per-minute rate cap.''

89. We seek comment on prohibiting separate ancillary charges for functions that are typically a part of normal utility overhead and should be included in the rate for any basic ICS offering. These functions should include account establishment by check or bank account debit; account maintenance; payment by cash, check or money order; monthly electronic account statements; account closure; and refund of remaining balances. Separate charges for such ancillary services can often represent unreasonable practices and result in unfair compensation. For example, the record indicates that GTL currently requires a minimum deposit of $25 to create a prepaid collect account for an inmate's family member. If the customer does not spend the $25 in the account, GTL charges a $5 refund charge that is only triggered once the customer asks for a refund. If the account remains inactive for 180 days, the remaining funds become the property of GTL. We seek comment on prohibiting separate charges for these functions and on whether separate charges for other services should also be prohibited. Would such prohibitions help ensure just and reasonable ICS rates and fair, not excessive, ICS compensation?

90. The Alabama PSC implemented such an approach to the regulation of ancillary charges in its Further Order. It defined basic utility overhead services as including account set-up, account maintenance, account funding, payment by check or money order, monthly electronic billing statements, and refunds, declining to authorize separate fees for these services. The Alabama PSC took other steps to address fees and practices, including barring payment limits for certain forms of customer payments, barring wireless administration fees for linking wireless numbers to an account, and requiring providers to include up to five pre-approved numbers on the call list for prepaid ICS at no charge. In contrast, it authorized, but capped, separate ancillary charges for other services, including debit/credit card payment, payment via live agent, bill processing for collect calls billed by a call recipient's local telecommunications service provider, third party payment services, inmate canteen/trust fund transfers, and paper billing statements. We seek comment on whether the Alabama PSC's approach to prohibiting certain fees and capping others is reasonable and would lead to just and reasonable rates and fair ICS compensation. We also seek comment on the approach taken by the New Mexico Public Regulation Commission, which adopted a similar but more proscriptive approach, barring all fees except payment processing fees for credit card or check by phone payments and a refund fee.

91. We seek comment on other proposals in the record to reform ICS ancillary charges. The Wright Petitioners recommend prohibiting all ancillary charges but, if the Commission were to permit ancillary fees, it suggests adopting an approach similar to Alabama's and New Mexico's. The Prison Policy Initiative recommends ''ban[ning] all illegitimate fees.'' Several ICS providers also recommend

reforming ancillary charges. Pay Tel recommends that ancillary charges be ''generally prohibited, subject to a narrow list of clearly-defined exemptions,'' particularly ''fees associated with the processing of payments.'' CenturyLink suggests similar treatment. Securus proposes eliminating all mandatory fees, bill statement fees, federal regulatory recovery fees and state cost recovery fees, and capping all convenience fees, including transaction funding fees, for five years.

92. We also seek comment on the Joint Provider Reform Proposal, which includes a proposal ''that ancillary fees are limited to a specified list of permissible fees,'' proposing to eliminate a number of types of fees, including per call fees, account set-up fees, billing statement fees, account close-out and refund fees, wireless administration fees, voice biometrics and other technology fees, and regulatory assessment fees and the capping of rates for remaining fees. The Proposal also requires providers to offer free payment processing options such as payment by check or money order when offering single call payment options. The Alabama PSC raised concerns with the Joint Proposal, including its treatment of site commissions, proposed rate caps that purportedly overcompensate providers serving prisons, and proposed ancillary fees that it asserted would result in substantial net revenue increases for providers. Pay Tel also identified concerns with the Proposal, stating that it ''lacked legitimacy from a number of perspectives'' and ''would allow the Proposers . . . to continue to burden inmates and their friends and family with excessive fees and practices that significantly and unjustifiably increase the cost of ICS.'' The Alabama PSC's and Pay Tel's concerns are addressed at greater length below. Will the suggestions in the Joint Provider Reform Proposal result in just and reasonable rates for consumers and fair, not excessive, compensation? If the use of ancillary charges was driven by pressure from increasingly high site commissions and the Commission were to prohibit site commissions, is there continued justification for allowing providers to assess ancillary fees generally?

93. If the Commission were to prohibit some ancillary charges, should ICS providers be required to seek prior Commission approval before assessing a new ancillary charge? If so, what should such an approval process involve and what information should providers file? Certain states already require prior approval of new ancillary charges. Should states continue to play such a role even if the Commission regulates ICS ancillary charges? In lieu of seeking approval, should ICS providers file a notice about a change such as 60 days before? If we take this approach, should the new fee be allowed to go into effect absent Commission or a state action? We seek comment on these approaches, including the administrability and relative burden associated with each approach.

b. Rate Caps for Ancillary Charges

94. We seek further comment on whether the Commission should set rate caps for ancillary charges that it finds permissible to ensure those charges are just and reasonable and ensure fair compensation. Commenters, including some ICS providers, support the use of rate caps. Some commenters note with approval the Alabama PSC's Further Order that capped rates for ancillary charges it allows. For example, the Wright Petitioners support the use of rate caps for ancillary charges if the Commission decides to authorize them, and cites with approval the two states that already proposed taking such a step. Would either the Alabama PSC's or the New Mexico PRC's approaches to capping ancillary charges be appropriate models for the Commission to consider? If the Commission were to establish rate caps for ancillary charges it did not prohibit, what would be appropriate levels for such rate caps? We seek comment specifically on the Alabama PSC's rate caps for debit and credit card payment fees via the web, an IVR, or a kiosk ($3.00 maximum) and for live operator assisted payments ($5.95 maximum). NCIC and Pay Tel expressly support ancillary charge rate caps at these levels, as other ICS providers reportedly have. How do these rate caps compare to providers' costs?

95. In the alternative, we seek comment on whether we should prohibit separate ancillary fees and instead permit the recovery of such costs using a per minute rate cap. The data submitted by ICS providers on the cost of processing financial transactions yields a wide range of per-minute costs. We seek comment on establishing a per-minute ancillary charge rate cap or safe harbors. If so, how should these charges be set and what level is appropriate? If so, what would permanent rate caps inclusive of such charges be?

96. We also seek comment on the Joint Provider Reform Proposal which proposes to (1) cap deposit fees to fund prepaid and debit ICS accounts at $7.95 for three years, (2) allow providers to charge a $2.50 administrative fee to process payments made through third party payment processing companies such as Western Union and MoneyGram in addition to the fees they charge, (3) allow providers to charge a per call validation fee of eight percent to compensate providers for call-specific security functions, and (4) cap fees for ''convenience or premium payment options'' for single call services at current rates for three years. The Alabama PSC generally opposes these fee proposals. AmTel agrees and asserts that the ''Proposal is very misleading and will not lower prices to inmate families.'' Pay Tel comments that the consumer benefits of the proposed ancillary fees' 'reduction' are illusory. For example, Pay Tel suggested that ''[v]alidation is a legitimate expense, but one that is included in Pay Tel's normal cost of providing service. In no event does this expense rise to the level of 8% of gross call revenue.'' We seek comment on whether these proposals would ensure reasonable rates and fair compensation. How do these proposed caps compare with providers' costs? How do they compare with previous proposals made by ICS providers?

97. The following table is provided as a means of facilitating comparison of several of the ancillary charge reform proposals referenced herein. The fees included in this table represent a non-exhaustive list of fees addressed in the various proposals.

TABLE TWO

	Ancillary charge proposals		
	Alabama PSC further order	ICS provider reform proposal	Pay Tel proposal
Check/money order payment	No charge	No charge	No charge.
Debit/credit card payment or deposit fees.	$3.00 cap (web/IVR) $5.95 cap (live operator)	$7.95 cap for 3 years	$3.00 cap (web/IVR). $5.95 cap (live operator).

TABLE TWO—Continued

	Ancillary charge proposals		
	Alabama PSC further order	ICS provider reform proposal	Pay Tel proposal
Single call/single payment services	Sum of $3.00 cap on bill processing fee plus capped per minute charge for a 12 minute call.	Cap at existing fees (as high as $14.99 billed to card, $9.99 billed to cell phone) for 3 years.	Jails (ADP 1–349): $6.12. Jails (ADP 350+): $5.64. Prisons: Prohibit service.
Account set-up, maintenance, closure, and refund fees.	Prohibited	Prohibited	Not addressed.
Bill processing fee for collect calls (by call recipient's carrier).	$3.00 cap	Not addressed	Not addressed.
Bill statement fee	No charge for electronic bill. $2.00 cap for paper bill.	Not addressed	No charge for electronic bill. $2.00 cap for paper bill.
Money transfer fees	Fees above $5.95 require affidavit and are subject to investigation.	Existing fees (as high as $11.95) plus an additional administrative fee capped at $2.50.	$5.95 cap (Western Union). $5.65 cap (MoneyGram). No additional fee.
Regulatory cost recovery fees	State regulatory cost recovery fees prohibited.	Various regulatory cost recovery fees prohibited (but ''federal and state regulatory fees'' allowed).	Not addressed (but pass through government mandated taxes and fees).
Security fees	Allow separate security biometrics fee.	Validation fee of up to 8% per call. Prohibited fees include VINE, location validation fees, voice biometrics fees, and technology fees.	$0.02 per minute voice biometric fee (only where deployed; lower in prisons). Vendors may apply for new technology fees.

c. Charges for Other Services

98. *Single Call Services.* ICS providers also make available so-called single payment or single call services. These services enable the billing of ICS collect calls through third party billing entities on a call-by-call basis to parties whose carriers refuse to bill collect calls. The Alabama PSC addressed single call services in its Further Order, asserting jurisdiction over intrastate single call services and capping the rates ICS providers may charge for them. By some accounts, the use of single call services has increased dramatically, particularly since the adoption of the *Inmate Calling Report and Order and FNPRM.* One commenter stated that such services have recently been estimated to account for as much as 40 percent of provider revenues. We seek further comment on the prevalence of the use of single call services in the ICS industry. Have such services become more prevalent in the market since the Commission's *Order*? If so, why? Are such services effectively an end run around the Commission's rate caps or are customers fully apprised of the higher costs and select such services for convenience or value? We also seek comment on how significant a role such services play in the ICS market today and what usage trends for such services are likely to be.

99. While ICS providers appear to offer single call services under a variety of names, they appear to be generally two types. The first involves a one-time credit or debit card payment to enable the completion of a single collect call to a wireline phone. Examples of this type of single call service include Securus' ''Pay Now'' and GTL's ''Collect2Card'' services, both of which are priced at a flat rate of $14.99 per call, substantially higher than the Alabama PSC's proposed interim intrastate rate caps. A second type of single call service involves a similar payment arrangement for the completion of a single collect call to a wireless phone, the charge for which is confirmed by a text message to the called party's wireless phone. Examples of this type of single call service include Securus' ''Text2Collect'' and GTL's ''collect2phone'' services, both of which are priced at a flat rate of $9.99 per call, also well above the Alabama PSC's intrastate rate caps, as well as the Commission's interstate rate caps. Do charges for such services circumvent or violate either set of rate caps or are such services sufficiently distinct from collect ICS to warrant separate pricing? Both types of single call services are charged on a flat rate basis, regardless of call duration, further distorting the effective per-minute charge consumers pay and raising concerns about multiple charges in the case of inadvertent call disconnection. Consumers using these services may be unaware that they could dramatically reduce the charges for ICS simply by establishing an account with an ICS provider. Some ICS providers have been successful in educating consumers on lower cost options. We seek comment on whether these rates are just and reasonable and whether they ensure fair and not excessive compensation for providers. We also seek comment on whether ICS providers incur additional costs in providing single call services, and if so, what they are.

100. Providers have challenged the Alabama PSC's jurisdiction over both types of single call services. In the case of single call services to wireline phones, ICS providers disputed the Alabama PSC's authority to regulate such services, citing interference with their contractual relationships with third party billing and payment processing entities which typically contract with ICS providers to provide the service. The Alabama PSC characterized these entities as ''third party billing aggregators'' which performed the ''the billing and delivery functions for ICS calls.'' We seek comment on the nature of these services and the types of functions such entities provide. For example, do these third parties perform functions analogous to those performed by third party billing entities used by local exchange carriers? Do the third parties actually contribute any facilities or services used to provide these services? The Alabama PSC also noted that ICS providers advertise and provide these services in their own name and bills refer consumers to an ICS provider Web site. The Alabama PSC determined that it had ''jurisdiction over the charges for collect calls originating from Alabama confinement facilities regardless of any intermediaries the ICS provider chooses to include prior to call termination.'' We seek comment on whether Commission regulation of single call services would

not impermissibly infringe on such contractual relationships.

101. In the case of single call services to wireless phones, ICS providers have asserted that such services are not subject to state commissions' authority since they entail the use of a text message to confirm the source and charges for the call and involve calls to wireless phones, the rates for which are not subject to state jurisdiction. We seek comment on the concept that neither the fact that such calls are preceded by a text message nor the fact that the called party uses a wireless phone alters the nature of the ICS provided. If, however, the Commission were to determine that either of these factors is relevant to determining the nature of the ICS, we seek comment on whether the Commission's section 276 jurisdiction over all forms of ICS give it authority to regulate such services.

102. The Alabama PSC set a rate cap for single call services at a flat rate amount that included a billing or payment charge capped at $3.00 per call and a usage charge derived from its per-minute rate caps. We seek comment on this approach. Should the Commission adopt a rate cap for single call services? Should ICS providers be required to charge a per-minute rate on the basis of actual call duration? Should the rates for such calls reflect the per-minute charge for collect calls along with an appropriate bill or payment processing fee? Should there be a transition period to allow providers to adapt their single call service offerings? Are ICS providers required to publish on their Web sites their charges for single call services and notify consumers of the option of establishing an account to obtain a more reasonable rate? Alternatively, should these services be considered ancillary services?

103. *Money Transfer Services.* The *FNPRM* sought comment on fees assessed by third parties such as Western Union and MoneyGram to process debit and prepaid account payments for ICS. The Prison Policy Initiative previously noted that third party payment processing fees for the provision of ICS are typically higher than such fees in other industries and suggested that ICS providers were receiving compensation from such third party service providers. We seek comment, data and other evidence on how prevalent the use of third party money transfer services is and what percent of account funding is accomplished through such services. We also seek comment on the Alabama PSC Proposed Order which acknowledges that money transfer ''fees are set by these financial services but [the PSC] is also aware that agents hosting such services are paid a portion of the fee.'' The Alabama PSC Proposed Order states that ''ICS providers are prohibited from receiving any portion of fees paid by their customers to third-party financial services.'' It also proposed a rate cap of $5.95 per transaction, above which providers would face an investigation of their rates and potential refund liability. Similarly, CenturyLink suggests that ''[c]ertain consumer-optional third party fees such as Western Union charges should be allowed, but without mark-ups, revenue sharing arrangements or volume rebates.'' In contrast, the Joint Provider Reform Proposal suggested adding an additional administrative fee of a maximum of $2.50 per transaction on top of existing money transfer fees. We seek further comment on these proposals and on whether ICS providers' receipt of payments from payment processing companies in connection with their provision of ICS represents an unreasonable practice under section 201(b) or results in unfair compensation under section 276.

104. We seek comment on how the Commission should ensure that money transfer service fees paid by ICS consumers are just and reasonable and represent fair compensation. Are money transfer services ancillary services under section 276(d)? Are they a practice that causes unjust rates or unfair compensation? Are such charges encompassed by the definition of ''ancillary charges'' in the Commission's rules? To the extent they involve charges placed by a third party on a call recipients' phone bill, are they analogous to third party fees that are the subject of our ''cramming'' rules? To ensure just and reasonable rates and fair compensation, should the Commission prohibit ICS providers from entering into revenue sharing arrangements with money transfer services, receiving payments from such services, or including the costs of such services in their rates? To enforce a similar prohibition, the Alabama PSC proposes to require ICS providers operating in the state to report the payment transfer fees third parties charge their customers. It also proposes to require providers to justify fees over $5.95, and subject such fees to investigation and potential refund liability. Should the Commission adopt a similar enforcement mechanism? Should it allow states to enforce such a mechanism? What impact would any such requirements have on contracts between ICS providers and third party money transfer services? The Alabama PSC notes that, according to its research, contracts between ICS providers and Western Union may be cancelled on 30 days' notice. It also notes that Western Union contracts with providers include a provision requiring vendor compliance with all regulatory requirements and laws. Do commenters' experiences confirm the Alabama PSC's observations? Are there other approaches to enforcement that the Commission should consider?

105. *Regulatory Recovery Fees.* Commenters have previously highlighted ICS providers' use of fees to recover the cost of regulatory compliance. The amount of such fees industry-wide can be quite substantial. The Alabama PSC noted that ''[s]everal ICS providers presently absorb regulatory costs electing not to charge consumers a separate recovery fee'' and barred separate intrastate regulatory fees, stating that their rate caps were ''sufficient to recover reasonable regulatory costs incurred by the provider.''

106. A number of ICS providers have also opposed the use of regulatory recovery fees. The Joint Provider Reform Proposal recommends eliminating various types of regulatory recovery fees and does not include such a fee among the fees it proposes to retain. Pay Tel, in its advocacy before the Alabama PSC, stated ''these expenses are a cost of doing business reflected in the overall average cost per minute. Pay Tel supports the prohibition of such fees.'' Securus proposes to eliminate its Federal and State regulatory recovery fees. We seek comment on whether the cost of regulatory compliance should be considered a normal cost of doing business and as such should be recovered through basic ICS rates, not additional ancillary fees. In the alternative, if the Commission permits the separate recovery of regulatory fees, should it require that they be broken out as a line item on an ICS end users' billing statement?

107. *Security Fees.* Some ICS providers suggest that the Commission allow fees to recover new security technology expenses for correctional institutions. The Joint Provider Reform Proposal proposed the elimination of three or four types of fees likely related to security and the retention of a single technology-related fee. However, as part of its comprehensive proposal, Securus suggests that providers be allowed to charge ''incremental product pricing above rate caps if necessary'' for ''safety and security features'' and proposes such charges ''be filed with [the] FCC for approval.''

108. We seek comment on whether security costs represent a core function in the provision of ICS, the costs of which should be included in rates and not as ancillary fees. The Commission's interim interstate rate caps were based on ICS providers' cost data that included the costs incurred in developing, deploying and provisioning security features. The *Order* also expressly accounted for the cost of continuous voice biometrics in its debit and prepaid rate cap it adopted. Pay Tel's Proposal suggests that a voice biometric fee of $0.02 per minute be applied to its proposed rates. If the Commission were to allow providers to assess customers separate ancillary charges for such services, how would it evaluate providers' claims regarding the need for such functions or their cost? How would it ensure that ICS providers were not recovering the cost of security features twice—once through their rates and again through an ancillary charge—short of a full analysis of the provider's costs? If the Commission were to allow separate fees to recover security costs, should it require prior approval or 60 days' notice for such charges?

d. Consumer Disclosures

109. We also seek comment on how to ensure that rates and fees are more transparent to consumers. We therefore seek comment on the requirement that ICS providers notify their customers regarding the ICS options available to them and the cost of those options. One ICS provider underscores the importance of ''educating the consumer, giving them the choice, what's the most economical way if they want to get money on an account and do it quickly.'' The same provider states that when it advertises on its Web site the most economical way to fund ICS calls, a substantial percent of its customer base uses that method, reducing consumer expense significantly. ICS providers that offer interstate toll service are already required to post their rates on their Web sites and, to the extent they offer inmate operator services, their live agents are already required to make certain notifications to customers. Should providers' Web sites, automated IVRs, and live agents be required to offer in a more prominent fashion no-cost or lower-cost options available to consumers before offering other, higher-priced optional services? To what extent would any such regulation implicate the First Amendment? Should the Commission take other steps to ensure consumers are aware of lower-priced service options?

110. The Joint Provider Reform Proposal acknowledged existing requirements to publish ancillary fee rates on providers' Web sites and offered a detailed proposal regarding notification requirements for financial transactions, including:

- The ICS provider shall fully inform customers of all payment methods available (including the no-charge option), the payment processing charges associated with each payment method, and the estimated time required to establish service applicable to each payment option.
- The ICS provider shall clearly and conspicuously identify the required information. The information should be presented clearly and prominently so that it is actually noticed and understood by the customer.
  - The ICS provider shall provide a brief, clear, non-misleading, plain language description of the required information. The description must be sufficiently clear in presentation and specific enough in content so that the customer can accurately assess each of the available payment methods.
  - An ICS provider shall clearly and conspicuously disclose any information the customer may need to make inquiries about the available payment methods, such as a toll-free number, email address, or Web site address by which customers may inquire or dispute any charges. An ICS provider shall include any restrictions or limitation applicable to each payment method available.

In its proposal Pay Tel suggests that:

- Vendors must post facility-specific rates and fees for all services, to be visible to inmates on-site and to consumers on the Vendor Web site prior to setting up an account.
- Vendor Web sites must provide a link to the FCC Enforcement Bureau Web site and the applicable State Regulatory Agency Web site.
- Posting/Notice Must Include:
  - Call rates and transaction fees (at time of call, printed material available at facility, Automated IVR, Live Agent & Web site).
  - Refund instructions (Web site).
  - Terms and conditions for service (Web site).
  - Cost information for calls, email and messaging services, video visitation and any other communication services offered (Web site).

We seek comment on these proposals as they relate to ICS financial transactions and more generally to ICS practices in general. We also seek comment on alternative proposals to make rates and fees more transparent to inmates, their families, friends and other users of inmate calling services.

e. Other Issues

111. Some ICS providers impose additional policies beyond their assessment of ancillary fees that further restrict consumers' access to ICS. In regard to such policies, CenturyLink expresses the concern that ''policies such as funding minimums and maximums, prepaid account refund requirements, and account expiration policies must be tightly controlled to avoid gaming.'' We seek comment on whether we should prohibit ICS providers from these and similar practices that effectively limit end users' ability to access and use ICS. What other types of limiting practices should we prohibit or restrict to preclude such gaming?

112. GTL asserts that the Commission's Truth-in-Billing rules give providers flexibility to recover their costs either through rates or other line item charges. The Minnesota Department of Commerce asserts that ancillary charges that exceed a provider's costs are inherently deceptive and violate the Commission's Truth-in-Billing rules. We seek comment on whether it would be necessary to harmonize Commission regulation of ICS ancillary charges with its Truth-in-Billing rules. To the extent that such fees are not commensurate with providers' costs, does existing precedent support the view that those fees violate the Truth-in-Billing rules, or should we clarify that the fees are considered misleading and a violation of the Commission's Truth-in-Billing rules, unreasonable under section 201(b) or unfairly compensatory under section 276? Should the Commission clarify that pursuant to section 276, Truth-in-Billing rules apply to all ICS providers, including any that may claim they provide VoIP services?

D. Additional Ways To Promote Competition

113. Over the last 30 years, real competition, as opposed to rate regulation, has been the preferred method to advance consumer protection, lower rates, increase feature and functionality of equipment and services, reduce the government involvement and costs, and improve the overall consumer experience. To date, however, correctional facilities generally have not permitted competition for consumers within the ICS market.

114. As an alternative to the ideas explored in this item to reduce inmate calling rates, we continue to explore whether the advent of competition within the inmate facilities may provide

a different course of action. The 2013 *Inmate Calling Report and Order and FNPRM* sought comment on how to promote competition within the correctional facilities, but the Commission received insufficient information in response to the questions posed, so we seek to provide more targeted questions in order to solicit further responses. Accordingly, we seek further comment on ways to remove barriers to entry and promote competition in the ICS market. Aspects of the current ICS market appear to contribute to the market failure. One is the practice of site commission payments, and we seek comment above on whether, and under what authority, the Commission should restrict such payments. Another is the fact that correctional facilities award ICS providers exclusive contracts and therefore do not permit competition within the facilities. The Commission previously sought comment on the impact of exclusive contracts and whether they should be prohibited. While some commenters opposed the idea due to security and cost concerns, another commenter suggested that the Commission revisit whether those concerns continue to justify exclusive contracts in light of technological advances. We seek additional comment on these views. Moreover, some commenters have questioned whether facilities incur any additional costs for the provision of ICS and we seek comment above on quantifying these costs. If facilities do not incur costs when there is one provider, what additional costs are incurred by introducing multiple providers? We ask commenters to specify and quantify any additional costs.

115. We also seek comment on whether there are other barriers and, if so, what steps we should take to address them and under what authority. For example, are there ways to allow greater competition within ICS without banning exclusive contracts? Are providers willing to compete on price, quality of voice and/or video service, service disruption and outage rates, and other factors that would be applicable with multiple providers? Would multiple providers be willing to serve an inmate facility if there is already an established provider? What impact could new technologies have on competition within inmate facilities?

E. Harmonization of State Regulations Under Section 276(c)

116. In this section, we seek comment on how state reform of ICS may be harmonized with any federal framework we may adopt and on the continuing roles states should play in advancing ICS reform. In the *FNPRM,* the Commission ''tentatively conclude[d]'' that section 276 ''affords the Commission broad discretion to . . . preempt inconsistent state requirements.'' In response, some commenters opposed state preemption, while others supported it as crucial to the Commission's reform efforts. While we seek comment on whether it is necessary to have a comprehensive framework for interstate and intrastate ICS, we nonetheless seek comment on how consistent state regulation of ICS could be harmonized with our framework. For example, should we establish guidelines regarding what a state would have to do on ICS reform to not be preempted? What would those guidelines include? Should we include reform of site commission payments, rate caps, actions addressing state prisons, as well as county or city jails?

117. We recognize the substantial ICS reform already accomplished in a handful of states such as Alabama, New Jersey, New York, and New Mexico. Such states have provided important leadership in the effort to reform ICS. In the *FNPRM,* the Commission commended such states and ''encourage[d] more states to eliminate site commissions, adopt rate caps, disallow or reduce per-call charges, or take other steps to reform ICS rates.'' In her opening remarks at the 2014 ICS Workshop, Commissioner Clyburn urged states to ''follow the FCC's lead, grab the baton, and enact their own reforms.'' Some states have taken steps to advance ICS reform since the release of the *Order.* New Jersey, for example, has set lower rates for ICS. Alabama has recently proposed comprehensive regulation of intrastate ICS. However, the vast majority of states have not taken up our repeated calls for ICS reform. In addition, states have inconsistently addressed site commission payments. For example, while the *Order* noted seven states that had eliminated site commissions for intrastate ICS, by implication the vast majority have not. We again encourage states to act on ICS in their jurisdictions and note that state action that is consistent with the regulations that the Commission ultimately adopts would not be subject to preemption. We also recognize, however, that most states either cannot or will not act and the Commission must adopt a nationwide framework to apply in these states to ensure that ICS rates are just, reasonable and fair.

118. We seek more focused comment on section 276(c), which states in reference to payphone regulation that ''[t]o the extent that any State requirements are inconsistent with the Commission's regulations, the Commission's regulations on such matters shall preempt such State requirements.'' We believe that the Commission has broad discretion to find that a particular state requirement, or category of state requirements, is either consistent or inconsistent with Commission ICS regulations under section 276(c). We also seek comment on the whether preemption is self-effectuating under section 276(c) and will occur automatically as a consequence of the inconsistency.

119. If preemption is not self-effectuating, and there is no Commission decision defining the scope of any inconsistency between federal and state requirements, how would states and other parties know that a particular state requirement had been preempted because it was inconsistent under section 276(c)? In the absence of a prior Commission decision, should any disputes regarding the inconsistency of a state requirement be resolved by the Commission on a case-by-case basis: e.g., through declaratory ruling or the section 208 complaint process? Are certain types of state requirements inherently ''inconsistent''? Other preemption provisions in Title II of the Act require the Commission to make certain decisions before a state law can be preempted, whereas section 276(c) does not directly address the issue.

120. *Exemptions to Preemption.* To encourage states to reform ICS, the *FNPRM* also sought comment on possible exemptions to preemption, asking whether ''the Commission [should] only take action to reform intrastate ICS rates in states that have not reformed rates to levels that are at or below our interim safe harbor.'' We expand on this concept here. What specific types of state actions to reform ICS should the Commission interpret as consistent with its regulations? Should, for example, the Commission list scenarios in which state regulations would be presumed to be consistent with the federal framework, such as when states address site commissions and reform ancillary charges? If so, what should the Commission consider ''reform'' or ''partial reform'' in this context? For example, we note that the Alabama PSC proposes capping ancillary fees but maintaining site commission payments. If the state regulates ICS rates in a manner that is consistent with Commission regulations, but regulates ancillary services in a manner inconsistent with Commission regulations, would all state regulations be viewed as preempted, or

would just the regulation of ancillary services be treated as preempted? To the extent the question would depend on how the Commission crafts its regulations, should the Commission design them in a way that makes inconsistency regarding one dimension severable from consistency regarding other dimensions? If so, how?

121. One *FNPRM* commenter suggests a ''cooperative federalism'' approach that would allow ''states to regulate intrastate rates provided that the regulatory framework complies with the core principles contained in the Order.'' We seek further comment on this and other approaches to harmonizing federal and state ICS reform. Some states have adopted laws that effectively require intrastate ICS rates to be provided at below-cost rates, with the difference presumably to be recouped by charging interstate rates that are set significantly above costs. Would any such state laws that require below-cost intrastate ICS rates be consistent with a Commission cap on intrastate ICS rates, even if the state rate was more ''aggressive'' than the Commission cap? For example, if the Commission adopts a per-minute cap on ICS rates, should states be free to regulate the level of per-call and per-minute charges for intrastate ICS so long as the resulting charge for a call of a particular duration is within the Commission's cap? Should states have other flexibility as it relates to site commission payments, ICS rates, charges for ancillary services, or other ICS regulation? If so, how can the Commission craft its regulations so that such state ICS reforms are interpreted as being consistent with its regulations? Should the Commission be concerned that some state reform actions could undercut the market-based approach that we seek comment on herein? How would the Commission then balance the benefits of encouraging state reform efforts with the need to ensure just and reasonable rates and fair compensation for ICS, as required by sections 201 and 276 of the Act?

122. If the Commission's final ICS rules are silent on certain issues (for example, arguendo, quality of service regulation), we seek comment on how the Commission should interpret state rules. Does the Commission have broad authority to enforce section 276(c) on a case-by-case basis even in situations where it has not previously adopted an applicable rule or provided relevant guidance? If a state commission has an active ICS proceeding, is it consistent with section 276(c) to permit the state commission a reasonable period of time to complete its proceeding prior to a Commission determination of whether such state reform is consistent with Commission reform? What might constitute such a reasonable period of time?

F. Existing Contracts

123. *Background.* The Wright Petitioners previously discussed the possibility of a one-year fresh look period, essentially a one-year period during which existing ICS contracts may be revised regardless of terms within the contracts that may prohibit such action. The Commission sought comment on this proposal in the *2012 ICS NPRM.*

124. In the *Order,* the Commission did not directly override existing contracts between correctional facilities and ICS providers. Rather, the Commission noted that if ''any particular agreement needs to be revisited or amended . . . such result would only occur because agreements cannot supersede the Commission's authority to ensure that the rates paid by individuals who are not parties to those agreements are fair, just, and reasonable.'' The Commission acknowledged that ''[t]o the extent that the contracts contain 'change of law' provisions, those may well be triggered by the Commission's action today.''

125. *Discussion.* We seek comment on the implementation of the requirements adopted in the *Order* and their impact, if any, on ICS contracts. The record indicates that the interim rates were implemented with little to no contract renegotiation. The record also indicates that several ICS providers have unilaterally made decisions about site commission payments without initiating contract renegotiations or cancellations. Is this accurate? We seek comment on any challenges associated with these practices. To the extent that commenters suggest alternatives to the regulatory approaches discussed above that could modify or otherwise affect existing agreements, we seek comment on the Commission's authority to take such action, why it should exercise such authority, and how any modification or other effect on existing agreements should be implemented.

126. We seek comment on a transition period for comprehensive ICS reform. Given the transition that we seek comment on herein, we seek comment on whether we should retain the approach in the *Order* and allow for change-of-law provisions to govern changes or whether we should take an alternative approach with respect to existing contracts. Should we allow for a ''fresh look'' to enable providers to renegotiate contracts or do most contracts include change-in-law provisions so a fresh look is not warranted? If the Commission adopts a transition period for existing ICS contracts, should it stagger the transition period as previously suggested by Telmate? Specifically, Telmate suggests that ''[s]taggering the fresh look window among the many thousands of ICS contracts nationwide . . . [is] the only practical way to harmonize the existence of long-term contracts and the unreasonable burden on smaller ICS providers in competing for correctional facility business at thousands of locations at the same time nationwide.'' If so, should the Commission stagger any transition period based on contract expiration dates or some other metric?

127. Alternatively, we seek comment on whether we should abrogate ICS contracts or modify particular terms of such contracts. Will abrogation of contracts that are focused on site commission payments better enable the market-based approach described herein to be implemented? In the *Order* the Commission concluded that it has the authority to abrogate or modify contracts. We seek comment on our legal authority to do so. In the alternative, should the Commission grandfather existing ICS contracts for some period of time and then allow them to expire? Given that ICS contracts are often multiple years in duration, is it consistent with the statute's requirement that ICS rates be just, reasonable and fair if we allow such rates to continue for an extended period of time? Are there ways the Commission could mitigate the possible disadvantages of a grandfathering approach? We seek comment on these issues, including our legal authority for each approach.

G. Transition Periods

128. In the *Order,* the Commission delayed the effective date of the new rules until 90 days following publication in the **Federal Register** to give parties ''time to renegotiate contracts or take other appropriate steps.'' The *FNPRM* sought further comment on ''how the Commission should proceed in establishing ICS rates for interstate and intrastate ICS.'' Comments were mixed. Several commenters requested that, if the Commission takes further steps toward ICS reform, it implement a transition period ''that is sufficiently long to enable correctional facilities to revise budgets and find replacement sources of funding.'' Conversely, one commenter opined that rate changes pursuant to the interim Order may have been accomplished through a simple notification letter from ICS providers to correctional facilities.

129. *Discussion.* The ICS providers that submitted the Joint Provider Reform Proposal suggest that ''[t]he new rate caps should become effective 90 days after adoption, along with any site commission reductions and ancillary fee changes outlined below.'' The providers that submitted the Proposal assert that ''[t]his period for implementation should ensure ICS providers and correctional facilities have adequate time to implement the new rate caps and any corresponding reductions in site commissions, including any contract amendments or adjustments that may be necessary.'' Pay Tel suggests a 90-day, after final order publication transition period for transaction fees, third party money transfer service fees, and ancillary fees and an 18-month transition period for jail and prison rate caps. Commenters advocating for a transition to the new rate caps should identify the appropriate transition and the justification for doing so.

130. We seek comment on whether 90 days after the effective date of the order is the appropriate transition to comply with all new requirements, including any rate caps, elimination of per-call charges, and ancillary fee changes for existing contracts. We also seek comment on whether any new ICS contracts entered into after adoption of an ICS reform order must comply with the terms of the order immediately after the effective date of the order.

131. In addition, we seek comment on a two-year transition period or at least one state or state subdivision budget cycle to transition away from site commission payments to allow facilities and states time to adjust. If we adopt a cost recovery amount for facilities, how should the transition be implemented in a manner that does not delay comprehensive reform? How would the transition work if the Commission gave a 90-day transition for rates to be at or below the cap, while allowing two years for site commissions to be eliminated? Would a period of two years allow sufficient time for correctional facilities to prepare for forthcoming ICS reform and its effect on their budgets? Or should we consider a longer transition such as a three year transition? Should the transition be shorter to minimize the potential for abuse? If so, should the transition be one year, the same as the 90-day transition to rate caps, or something else? The record suggests that site commission payments make up less than five-tenths of a percent of facilities' operating budgets. Securus suggests that site commissions should be completely eliminated by January 1, 2016 and rate reform should also be accomplished by that date. We seek comment on these proposals.

132. If the Commission adopts a two-year transition to the elimination of site commission payments, how should the payments be reduced? Should they be reduced in equal increments over two years, or should we align the reductions to state or state subdivision budget cycles? How have other states that reduced or eliminated site commissions implemented this change? Did they adopt a transition plan or implement the change immediately? We seek comment on whether any new contracts that include any potential cost recovery payments to facilities and a ban on site commissions that are entered into after the adoption of the final order be required to comply with the order. Should there be exceptions to a transition period based on whether interstate or intrastate rates are already below the prescribed rate level?

H. Accessible Inmate Calling Services

133. Our goal with ICS reform is to ensure that ICS is accessible to all inmates and their families at just and reasonable rates that represent fair compensation to ICS providers. Below, we seek focused comment on several disability access issues raised in the *Inmate Calling Report and Order and FNPRM* that merit further inquiry.

134. *Background.* In the *Order,* the Commission highlighted the telecommunications challenges faced by inmates who are deaf and hard of hearing, as well as by inmates communicating with family members or friends who are deaf and hard of hearing, such as extremely high rates for calls placed via the Telecommunications Relay Service (TRS). In the *Order,* the Commission ''clarif[ied] that ICS providers may not levy or collect an additional charge for any form of'' telecommunications relay services (TRS) call because ''such charges would be inconsistent with section 225 of the Act.'' However, the record indicates continuing problems, such as, for example, ''nearly half of deaf inmates surveyed did not have access to TTY at their facilities.''

135. In the *FNPRM,* the Commission sought comment on a number of questions to ensure that ICS is accessible. The Commission also tentatively concluded that inmate calling service rates per-minute for TTY calls should be set at 25 percent of the safe harbor rate for inmate calls, and sought comment on this proposal. The Commission sought comment on how ICS providers should recover the costs of providing such discounted TTY calls, and on the possibility of allowing ICS providers to recover the cost of a TTY call from the Telecommunications Relay Service Fund. In the Joint Provider Reform Proposal, the providers ''commit to continue to comply with their existing obligations'' under applicable laws, and ''also will work closely with correction facilities 'to ensure that deaf and hard of hearing inmates are afforded access to telecommunications that is equivalent to the access available to hearing inmates.' '' Pay Tel's Proposal states that ''ICS Vendors will work with confinement facilities where requested to enable video relay services,'' ''[c]omply with all existing obligations and laws regarding service people with disabilities,'' and ''[r]equire that deaf and hard of hearing inmates will have full access to TDD/TTY services at no additional charge.'' We seek comment on these proposals.

136. *Discussion.* In the *Order,* the Commission noted commenters' general agreement with the Commission's statement in the *2012 ICS NPRM* that TTY-to-voice calls take at least three to four times longer than voice-to-voice conversations to deliver the same conversational content, not including the time it takes to connect to the operator. In the *FNPRM,* the Commission tentatively concluded that ICS per-minute rates for TTY calls should be set at 25 percent of the interim safe harbor rate for standard ICS calls, and sought comment on this proposal. CenturyLink asserts that ''a discounted rate of 25% of the interstate safe harbor rate for TTY calls . . . is far too low. In CenturyLink's experience, TTY calls can take up to two times as long as regular calls, not the three or four times suggested by some commenters.'' HEARD, however, asserts that the proposed discounted rate is insufficient, as it ''does not account for varying literacy rates of deaf prisoners many of whom use sign language as their primary or only method of communication.'' HEARD urges a greater discount, based on the assertion that ''prison TTY telephone calls are typically at least six to eight times longer than a hearing phone call.'' We seek specific comment on the actual relative length of TTY-to-TTY and TTY-to-voice calls as compared to voice-to-voice calls. Given the wide range of assertions in the record, we request that comments be backed by data on the actual lengths of TTY-to-TTY, TTY-to-voice, and voice-to-voice conversations. Commenters should describe the methodology they used to collect the information with specificity.

137. The Commission has observed that, in implementing section 276 of the Act, section 276(b)(1)(A) exempts TRS

calls from the per-call compensation requirement, and it requires payphone service providers to provide free access to connect to TRS. However, if the outgoing portion of a TRS call is a long distance call, a caller is required to pay for that portion. Is it the case that no ICS provider charges inmates for voice-to-TTY or TTY-to-voice calls because the ''interexchange company holding the [state] TRS contract carries the call to the called party?'' If so, should final reduced ICS per-minute rates for TTY calls be applicable only to TTY-to-TTY calls, as those calls are indistinguishable from standard voice calls because the inmate is dialing the called party directly, using the called party's terminating phone number, and thus the call data looks identical to the call data from a typical voice call?

138. With respect to TTY-to-voice and voice-to-TTY calls, we seek comment on AT&T's request for clarification that the ''manner in which it handles operator-assisted collect calls from inmates via TRS'' is ''subject to the rate requirements set out in the order in WC Docket No. 12–375.'' AT&T describes the issue as follows:

> Pursuant to contract with state authorities, AT&T provides TRS service in eight states plus the District of Columbia. Often times, but not always, the TRS Communications Assistant (CA) can see that the call has originated from a detention facility. For security, operator services practices limit inmate calling to collect calls. Upon receiving the call, the inmate can direct the CA to forward the call to any interexchange carrier on the carrier of choice list. The CA in the states where AT&T provides the service is an AT&T employee. If the inmate selects AT&T as the IXC for the call, the CA then functions as the operator service provider and the called party will be charged at the tariffed rate for the call, which is higher than the rate cap for a collect call specified in the ICS order. AT&T interexchange collect calling toll services are not limited to inmates only; anyone making the same type of TRS collect call will be treated and charged in the same manner.

139. Section 64.6000 of our rules defines ICS as ''the offering of interstate calling capabilities from an Inmate Telephone;'' and Inmate Telephone as ''a telephone instrument or other device capable of initiating telephone calls set aside by authorities of a correctional institution for use by Inmates.'' We seek comment on whether AT&T and other entities that provide TRS are providing ICS for TRS calls placed by inmates. Is it relevant that ''TRS [communications] assistants may place only [operator assisted] collect calls on behalf of inmates using TRS?'' Would it be relevant if inmates are not charged for calling TRS, but only for the long distance component of a TRS call?

140. We seek further comment as to whether the rates and charges levied for operator-assisted collect calls from inmates via TRS are subject to the rate requirements set out in the *Order.* Does the fact that an inmate ''can direct the CA to forward the call to any interexchange carrier on the carrier of choice list'' indicate that the interexchange portion of the call is no longer ICS, and therefore not subject to our rate requirements?

141. TTYs are only one form of accessible equipment, and TTY relay is only one form of TRS, and commenters to the *FNPRM,* as well as some 2014 ICS Workshop participants, decry correctional facilities' continued reliance on TTY equipment, as well as their failure to make newer equipment technology such as videophones for Video Relay Service (VRS) and point-to-point video communications, devices for Internet Protocol Relay Service (IP Relay) and Internet Protocol Captioned Telephone Services (IP CTS), available to inmates. We seek comment on the availability of these technologies as well as any other advanced technologies that meet persons with disabilities communication needs in correctional facilities. Should all correctional facilities be required to install a certain type or types of equipment for inmates with disabilities, such as videophone equipment, IP CTS devices or other assistive technologies? Should they do so upon the request of an inmate with a disability? We seek comment on our authority to regulate correctional facilities in this manner. If correctional facilities are required to provide such equipment, how should the facilities recover the costs of purchasing and installing the necessary equipment, and how should ICS providers recover the costs of the calls? In the alternative, are ICS providers responsible for providing any communications equipment needed to meet the communications demands of all inmates regardless of ability? How would such a requirement fit into the Commission's section 225 authority? Do ICS providers meet criteria as a common carrier for offering telecommunications relay service eligible for cost recovery from the TRS Fund? Why or why not? And, if not, is there a justification for different treatment in this industry? Will ICS providers or facilities incur costs to install equipment for use by any inmate with a disability? What is the impact of such approaches on ICS providers? Should providers be able to recover any additional costs if they are unable to do so through the TRS Fund?

142. The Commission has imposed differing registration requirements for users of the various types of TRS. We seek comment on how the Commission's evolving relay service registration requirements can be met in an institutional setting where more than one user will be utilizing equipment. We also seek comment about security issues related to IP telephone technologies, such as VRS, IP-captioned telephone service, and IP Relay. Do these types of advanced technologies pose a security risk in a correctional setting? If so, what is the nature of such risk? Is the risk greater or lesser than that associated with traditional telecommunications and interconnected VoIP services utilized by ICS providers?

143. What are just, reasonable and fair per-minute rates for end users and ICS providers for forms of TRS other than traditional TTY TRS that will allow service to be accessible to all inmates regardless of ability? HRDC suggests that, consistent with section 225 of the Act, the rates for accessible communications technology from correctional facilities should be no more than calls made from traditional telephones. Would it be appropriate to discount the per-minute rate for ICS calls made using other accessible equipment or other forms of TRS, such as Speech to Speech relay services or Captioned Telephone Service, as previously proposed for TTY calls? Would different rate setting methodologies be appropriate given the differing nature of TTY and other forms of TRS?

144. *TRS Reporting Requirements.* In the *FNPRM* the Commission asked whether ICS providers should be required to submit TRS usage data and report on user complaints. Commenter HEARD asserts that ''nearly half of deaf inmates surveyed did not have access to TTY at their facilities'' and suggests that correctional facilities begin to track and report to the Commission the number of relay calls being made. We seek further comment on this proposal. Should ICS providers be required to report to the Commission the number of disability-related calls they provide, the number of problems they experience with such calls, or related complaints they receive? Or should any such data collection be more narrowly tailored as suggested by the Federal Bureau of Prisons? Should such data be part of the periodic review we seek comment on below?

I. Advanced Inmate Communications Services

145. We seek comment on newer technologies and services available for

inmate communications. We believe that our core goals for inmates and their families remain the same regardless of the technologies used—ensure competition and continued widespread deployment of ICS and the societal benefits that they bring. We expect that new technologies available in correctional settings—like new technologies available to consumers in the general public—should offer improvements and innovations that benefit users and thus serve our goals for ICS reform. In this section we seek comment on these newer technologies, on whether there are any pertinent differences that justify any differences in rules, and on the legal considerations that may need to be addressed.

146. *Background.* In the *FNPRM,* the Commission sought comment on ''the impact of technological advancements on the ICS industry.'' The Commission also invited comment on the Commission's legal authority to regulate the rates for services provided over newer technologies. In response, Pay Tel states that ''[t]here is no question that new technologies will continue to emerge that will affect and improve provision and quality of, and security related to, ICS.'' The Prison Policy Initiative suggests that there are benefits to advanced technologies in correctional settings such as video visitation systems (VVS), but cautions that there is ''clear evidence that the video communications market is currently driven by the same perverse incentives that caused market failure in the correctional telephone industry.''

147. At the Commission's 2014 ICS Workshop, MeshIP discussed its ''secure prison cell phone solution that gives detainees highly customized cell phones with all the security and control features of prison payphones.'' JLG Technologies described for the audience voice biometrics technology, the second generation of voice biometrics, known as continuous voice identification, and next generation voice biometrics technology currently under development. GTL believes the biggest technological trends in inmate communications will be access to wall-mounted, multiservice kiosks, which offer more frequent and better contacts with the inmates' families and friends and then a shift to hand-held devices.

148. *Discussion.* We seek a greater factual understanding of the availability of these and other services. What kinds of services are available? Are they available commonly in most facilities, or only in certain ones? What is the demand for these services and what rates and fees are charged? What additional functionalities do they offer? Do they provide any greater benefits to inmates, their families, or others, than traditional services? What are ICS providers' rates for other services such as email, voicemail or text messaging? The record indicates that some ICS providers offer tablet computers and kiosks that allow inmates to access games, music, educational tools, law library tools and commissary ordering. What is the compensation mechanism for access to these offerings?

149. Are there additional costs to ICS providers in developing, provisioning, or offering these services? Participants at the 2014 ICS Workshop suggest that there are ''huge challenges in anticipating and funding costs associated with developing, implementing, and maintaining these new systems and services.'' GTL noted that ICS providers bear the costs of the ''development for the kiosk, to put that device on the wall . . . to provide the additional bandwidth, to develop and do the software development research for the applications that go in that device, for the additional maintenance and support to support the device once it's on the wall.'' We seek comment on the costs of these services in general. We also seek comment on the rates and fees charged for their use.

150. We seek comment on whether there is a similar market failure for service provided by new technology as described above for existing ICS. For instance, in response to evidence of unreasonable rates, the Alabama PSC capped VVS rates at $0.50 per minute and VVS recorded message download at ''$1.00 for the first minute and $0.50 for each additional recorded minute.'' Do commenters consider these just and reasonable rates and fair compensation for VVS? We seek comment on Pay Tel's proposal that the Commission establish a discrete mechanism by which providers may seek approval for a separate ancillary charge related to some type of advanced technology. How would such a charge function in the context of the proposed reform of ancillary charges discussed above? Securus also suggests that the Commission allow for ''incremental product pricing above rate caps if necessary'' for ''[p]roduct [e]xceptions.'' Is such a separate mechanism necessary? If so, how do proponents of such a mechanism suggest that it function? Will advanced ICS technologies continue to be developed and deployed without a separate and discrete recovery mechanism? Finally, if the Commission were to adopt regulations for advanced technologies like video visitation and video calling, what is the best way to harmonize our approach with that of the states?

151. In the *Order,* the Commission found that the application of section 276 is not restricted to any one form of communications technology and made clear that reforms apply to ICS regardless of technology used to provision the service, such as IP-based and TDM-based provisioning. Some ICS providers are developing wireless options. We therefore seek comment on whether ICS provisioned through wireless technology will also be subject to any final reforms adopted by the Commission under section 276. We also seek comment on whether advanced services like video visitation service and video calling services constitute ''inmate telephone service'' within the meaning of the term in section 276. Given the technologically neutral nature of section 276 and the fact that video calling shares many of the attributes of traditional ICS, including the fact that it is a pay per use service involving real time, two-way voice communications, are these services ''inmate telephone service''? Does the Commission's recognition of video relay service as a reimbursable relay service under section 225 of the Act (defining the video service as ''functionally equivalent'' to traditional TRS) provide analogous support for including video calling as an inmate telephone service? To the extent any communications services available to inmates fall outside the statutory definition of ''inmate telephone service,'' what other sources of authority provide the Commission with the ability to ensure that rates are just and reasonable? Could such services be regulated pursuant to sections 201 and 202 to ensure the rates, charges, and practices associated with those services are just, reasonable, and not unreasonably discriminatory? Could regulation of these services be supported through the use of the Commission's ancillary authority? For example, the record shows that some correctional institutions have eliminated all in-person visitation and replaced it with video visitation. What if providers were to eliminate all payphone calling in favor of video calling and charged rates for those services far in excess of the Commission's rate caps? Would such a shift effectively void the section 276 requirement of fair compensation and preclude the Commission from discharging its statutory mandate?

J. Periodic Review

152. We seek comment on whether a periodic review of how the reforms we seek comment on above are impacting

ICS rates, demand, ancillary charges and site commission levels is essential to ensure that our adopted reforms are creating and maintaining the proper incentives to drive end user rates to competitive levels. We seek comment on the benefits of establishing a periodic review process.

153. In the *Order* the Commission adopted an Annual Reporting and Certification Requirement that included the submission of interstate and intrastate ICS rate and demand data as well as the average duration of calls. In the *FNPRM* the Commission sought further comment on adjusting ICS rates over time. In response, the Wright Petitioners suggested that the Commission ''adopt rules to review the interim rates no later than 180 days after the ICS providers have submitted their second round of data collected under Section 64.6060 of the Commission's rules.''

154. The ICS providers that signed on to the Joint Provider Reform Proposal suggest that ''ICS providers should be required to provide certain information to the Commission annually for three (3) years to ensure the caps on per-minute rates and any admin-support payments adopted are implemented as required.'' Specifically, they suggest that ''[s]uch information should include a list of the ICS provider's current interstate and intrastate per-minute ICS rates, the ICS provider's current fee amounts, the locations where the ICS provider makes admin-support payments, and the amount of those admin-support payments.'' We seek comment on this portion of the Proposal. In addition to the information suggested by the ICS providers, we suggest that providers also be required to file demand and call duration data. Finally, we seek comment on whether any information gathered for an annual review must be certified as accurate by an officer of the reporting company.

K. Enforcement

155. In the *Order,* the Commission described its standard enforcement authority as it relates to ICS. The Commission also made clear, and we remind interested parties, that the Commission's general section 208 complaint procedures apply.

156. The Commission also made clear that penalties or failure to comply with the Commission's rules may result in monetary forfeitures of up to ''$160,000 for each violation or each day of a continuing violation, up to a maximum of $1,575,000 per continuing violation.'' We seek comment on how to interpret ''violation'' for use in the ICS context in light of the reforms discussed herein. For example, would each non-compliant ICS rate charged by a provider be a single violation? Would the continued payment of site commissions to a correctional facility constitute a single violation? Would the imposition of one ancillary charge over any cap or caps ultimately adopted by the Commission to one consumer constitute a single violation?

157. Securus has urged the Commission to require that the CEO, CFO, and General Counsel of each ICS provider all certify to the companies' compliance with the Commission's ICS rules and regulations. In the *Order,* the Commission also adopted an Annual Reporting and Certification Requirement that required ''an officer or director of each ICS provider annually to certify the accuracy of the data and information in the certification, and the provider's compliance with all portions of this Order.'' We note that this rule was stayed by the D.C. Circuit so we have not evaluated the effectiveness or impact of such a certification. Should the Commission adopt such a requirement? How does such a certification requirement function with the proposed periodic review requirement we seek comment on above?

158. We seek comment on whether states should continue to exercise enforcement functions with respect to any state requirements that are consistent with the Commission's regulations. We seek comment on whether states should continue to exercise their enforcement functions with respect to any final rules that the Commission may adopt as part of comprehensive ICS reform. Should the Commission expressly allow states to exercise such enforcement authority, e.g., to be carried out through their complaint resolution process, or some other role in the oversight process of state commissions? If the Commission did so, what if any oversight role should the Commission adopt with respect to state proceedings involving the enforcement of Commission rules? Would our authority to provide for such a state role apply regardless of whether certain state laws have been found to be inconsistent with any ICS rules governing intrastate ICS?

L. Cost/Benefit Analysis of Proposals

159. Acknowledging the potential difficulty of quantifying costs and benefits, we seek to determine whether each of the proposals above will provide public benefits that outweigh their costs. We also seek to maximize the net benefits to the public from any proposals we adopt. For example, commenters have argued that inmate recidivism decreases with regular family contact. This not only benefits the public broadly by reducing crimes, lessening the need for additional correctional facilities and cutting overall costs to society, but also likely has a positive effect on the welfare of inmates' children. On the other hand, commenters have argued that eliminating site commissions would directly affect jail revenues and lead to a reduction in recreational and rehabilitation services provided to inmates by facilities. Such a reduction could produce its own wave of negative aftereffects that offset some of the purported benefits. Accordingly, we seek specific comment on the costs and benefits of the proposals above and any additional proposals received in response to this Second Further Notice. We also seek any information or analysis that would help us to quantify these costs or benefits. We request that interested parties discuss whether, how, and by how much they will be impacted in terms of costs and benefits of the proposals included herein. Additionally, we ask that parties consider whether the above proposals have multiplier effects beyond their immediate impact that could affect their interest or, more broadly, the public interest. Further, we seek comment on any considerations regarding the manner in which the proposals could be implemented that would increase the number of people who benefit from them, or otherwise increase their net public benefit. We recognize that the costs and benefits may vary based on such factors as the correctional facility served and the ICS provider. We request that parties file specific analyses and facts to support any claims of significant costs or benefits associated with the proposals herein.

IV. Procedural Matters

A. Filing Instructions

160. 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). Comments and reply comments on this Second *FNPRM* must be filed in WC Docket No. 12–375.

- 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).

B. Ex Parte Requirements

161. This proceeding 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. Memoranda must contain a summary of the substance of the *ex parte* presentation and not merely a list of the subjects discussed. More than a one or two sentence description of the views arguments presented is generally required. If the oral 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.

C. Paperwork Reduction Act Analysis

162. This document does not contain proposed information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4).

D. Initial Regulatory Flexibility Analysis

163. As required by the Regulatory Flexibility Act of 1980 (RFA), the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) for this Second Further Notice, of the possible significant economic impact on small entities of the policies and rules addressed in this document. The IRFA is set forth as the Appendix. Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed on or before the dates on the first page of this Second Further Notice. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, will send a copy of this Second Further Notice, including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).

V. Ordering Clauses

164. *Accordingly, it is ordered* that, pursuant to sections 1, 2, 4(i)–(j), 201(b), 276, and 332 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i)–(j), 201(b), 276, and 332, this Second Further Notice of Proposed Rulemaking *is adopted.*

165. *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.

166. *It is further ordered,* that pursuant to sections 1.4(b)(1) and 1.103(a) of the Commission's rules, 47 CFR 1.4(b)(1) and 1.103(a), that this Second Further Notice of Proposed Rulemaking *shall be effective* 30 days after publication of a summary thereof in the **Federal Register**.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Appendix

Initial Regulatory Flexibility Analysis

1. As required by the Regulatory Flexibility Act of 1980, as amended (RFA) the Federal Communications Commission (Commission) has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in this Second Further Notice of Proposed Rulemaking (Second Further Notice). Written comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on the Second Further Notice. The Commission will send a copy of the Second Further Notice, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA). In addition, the Second Further Notice and IRFA (or summaries thereof) will be published in the **Federal Register**.

A. Need for, and Objectives of, the Notice

2. In today's Second Further Notice the Commission seeks comment on additional measures it could take to ensure that interstate and intrastate inmate calling service (ICS) are provided consistent with the statute and public interest and the Commission's authority to implement these measures. The Commission believes that additional action on ICS will help maintain familial contacts stressed by confinement and will better serve inmates with special needs while still ensuring the critical security needs of correctional facilities of various sizes. Specifically, the Second Further Notice seeks comment on:

• Limiting site commission payments;

- Final interstate and intrastate ICS rate cap reform;
- Limiting ancillary charges;
- Harmonizing inconsistent state regulations pursuant to Section 276(c) of the Communications Act of 1934, as amended;
- Treatment of existing ICS contracts;
- Appropriate transition period;
- Accessible inmate calling services;
- Advanced inmate communications services;
- Periodic review of the industry;
- Enforcement; and
- Cost/Benefit analysis of proposals.

B. Legal Basis

3. The legal basis for any action that may be taken pursuant to the Second Further Notice is contained in sections 1, 2, 4(i)–(j), 201(b) and 276 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i)–(j), 201(b) and 276.

C. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

4. 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, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small-business concern'' under the Small Business Act. 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.

5. *Small Businesses.* Nationwide, there are a total of approximately 28.2 million small businesses, according to the SBA.

6. *Wired Telecommunications Carriers.* The SBA has developed a small business size standard for Wired Telecommunications Carriers, which consists of all such companies having 1,500 or fewer employees. According to Census Bureau data for 2007, there were 3,188 firms in this category, total, that operated for the entire year. Of this total, 3,144 firms had employment of 999 or fewer employees, and 44 firms had employment of 1,000 employees or more. Thus, under this size standard, the majority of firms can be considered small.

7. *Local Exchange Carriers (LECs).* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to local exchange services. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 1,307 carriers reported that they were incumbent local exchange service providers. Of these 1,307 carriers, an estimated 1,006 have 1,500 or fewer employees and 301 have more than 1,500 employees. Consequently, the Commission estimates that most providers of local exchange service are small entities that may be affected by our action.

8. *Incumbent Local Exchange Carriers (incumbent LECs).* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to incumbent local exchange services. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 1,307 carriers reported that they were incumbent local exchange service providers. Of these 1,307 carriers, an estimated 1,006 have 1,500 or fewer employees and 301 have more than 1,500 employees. Consequently, the Commission estimates that most providers of incumbent local exchange service are small businesses that may be affected by our action.

9. We have included small incumbent LECs in this present RFA analysis. As noted above, a ''small business'' under the RFA is one that, *inter alia,* meets the pertinent small business size standard (e.g., a telephone communications business having 1,500 or fewer employees), and ''is not dominant in its field'' of operation. The SBA's Office of Advocacy contends that, for RFA purposes, small incumbent LECs are not dominant in their field of operation because any such dominance is not ''national'' in scope. We have therefore included small incumbent LECs in this RFA analysis, although we emphasize that this RFA action has no effect on Commission analyses and determinations in other, non-RFA contexts.

10. *Competitive Local Exchange Carriers (competitive LECs), Competitive Access Providers (CAPs), Shared-Tenant Service Providers, and Other Local Service Providers.* Neither the Commission nor the SBA has developed a small business size standard specifically for these service providers. The appropriate size standard under SBA rules is for the category Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 1,442 carriers reported that they were engaged in the provision of either competitive local exchange services or competitive access provider services. Of these 1,442 carriers, an estimated 1,256 have 1,500 or fewer employees and 186 have more than 1,500 employees. In addition, 17 carriers have reported that they are Shared-Tenant Service Providers, and all 17 are estimated to have 1,500 or fewer employees. In addition, 72 carriers have reported that they are Other Local Service Providers. Of the 72, 70 have 1,500 or fewer employees and two have more than 1,500 employees. Consequently, the Commission estimates that most providers of competitive local exchange service, competitive access providers, Shared-Tenant Service Providers, and Other Local Service Providers are small entities that may be affected by our action.

11. *Interexchange Carriers (IXCs).* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to interexchange services. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 359 companies reported that their primary telecommunications service activity was the provision of interexchange services. Of these 359 companies, an estimated 317 have 1,500 or fewer employees and 42 have more than 1,500 employees. Consequently, the Commission estimates that the majority of interexchange service providers are small entities that may be affected by our action.

12. *Local Resellers.* The SBA has developed a small business size standard for the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 213 carriers have reported that they are engaged in the provision of local resale services. Of these, an estimated 211 have 1,500 or fewer employees and two have more than 1,500 employees. Consequently, the Commission estimates that the majority of local resellers are small entities that may be affected by our action.

13. *Toll Resellers.* The SBA has developed a small business size standard for the category of Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 881 carriers have reported that they are engaged in the provision of toll resale services. Of these, an estimated 857 have 1,500 or fewer employees and 24 have more than 1,500 employees. Consequently, the Commission estimates that the majority of toll resellers are small entities that may be affected by our action.

14. *Other Toll Carriers.* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to Other Toll Carriers. This category includes toll carriers that do not fall within the categories of interexchange carriers, operator service providers, prepaid calling card providers, satellite service carriers, or toll resellers. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 284 companies reported that their primary telecommunications service activity was the provision of other toll carriage. Of these, an estimated 279 have 1,500 or fewer employees and five have more than 1,500 employees. Consequently, the Commission estimates that most Other Toll Carriers are small entities that may be affected by our action.

15. *Payphone Service Providers (PSPs).* Neither the Commission nor the SBA has developed a small business size standard specifically for payphone services providers. The appropriate size standard under SBA rules is for the category Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 535 carriers have reported that they are engaged in the provision of payphone services. Of these, an estimated 531 have 1,500 or fewer employees and four have more than 1,500 employees. Consequently, the Commission estimates that the majority of payphone service providers

are small entities that may be affected by our action.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

16. In this Second Further Notice, the Commission seeks public comment on options to reform the inmate calling service market. Possible new rules could affect all ICS providers, including small entities. In proposing these reforms, the Commission seeks comment on various options discussed and additional options for reforming the ICS market.

E. Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered

17. The RFA requires an agency to describe any significant, specifically small business, alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): ''(1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rules for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.''

18. The Second Further Notice seeks comment from all interested parties. The Commission is aware that some of the proposals under consideration may impact small entities. Small entities are encouraged to bring to the Commission's attention any specific concerns they may have with the proposals outlined in the Second Further Notice.

19. The Commission expects to consider the economic impact on small entities, as identified in comments filed in response to the Second Further Notice, in reaching its final conclusions and taking action in this proceeding. Specifically, the Commission will conduct a cost/benefit analysis as part of this Second Further Notice and consider the public benefits of any such requirements it might adopt, to ensure that they outweigh their impacts on small businesses.

F. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

20. None.

[FR Doc. 2014–26922 Filed 11–20–14; 8:45 am]

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Part IV

Federal Communications Commission

47 CFR Parts 15 and 74
Unlicensed Use of TV Band and 600 MHz Band Spectrum; Proposed Rule

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 15 and 74

[ET Docket No. 14–165; FCC 14–144]

Unlicensed Use of TV Band and 600 MHz Band Spectrum

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission proposes and seeks comments on rules for unlicensed operations in the frequency bands that are now and will continue to be allocated and assigned to broadcast television services after the incentive auction, including fixed and personal/portable white space devices and unlicensed wireless microphones. The Commission also proposes and seeks comment on rules for the operation of unlicensed white space devices, and licensed and unlicensed wireless microphones in the 600 MHz Band, guard bands and duplex gap that will exist after the incentive auction.

DATES: Comments are due on or before January 5, 2015; reply comments are due on or before January 26, 2015.

FOR FURTHER INFORMATION CONTACT: Hugh L. Van Tuyl, Office of Engineering and Technology, (202) 418–7506, email: *Hugh.VanTuyl@fcc.gov*, TTY (202) 418–2989.

ADDRESSES: You may submit comments, identified by ET Docket No. 14–165, by any of the following methods:

- Federal Communications Commission's Web site: *http://fjallfoss.fcc.gov/ecfs2/.* Follow the instructions for submitting comments.
- Mail: Hugh Van Tuyl, Office of Engineering and Technology, Room 7–A162, Federal Communications Commission, 445 12th 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 detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *NPRM of Proposed Rule Making,* ET Docket No. 14–165, FCC 14–144, adopted September 30, 2014, and released September 30, 2014. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–A257), 445 12th Street SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street SW., Room, CY–B402, Washington, DC 20554. The full text may also be downloaded at: *www.fcc.gov*.

Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415 and 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).

Summary of NPRM of Proposed Rulemaking

1. The Notice of Proposed Rulemaking (NPRM) proposes and seeks comment on rules for fixed and personal/portable white space devices that would operate in: The frequency bands that are now and will continue to be allocated and assigned to broadcast television services (the ''TV bands''); the 600 MHz Band Plan spectrum that, following the Incentive Auction, will be designated as guard bands (including a duplex gap); the portion of that spectrum allocated and assigned to new part 27 licensees where wireless licensees have not commenced operations; and Channel 37. It also proposes rules for unlicensed wireless microphone operations under part 15 of the rules in the TV bands and 600 MHz Band Plan spectrum, and for licensed wireless microphone operations under part 74 of the rules in the 600 MHz Band Plan spectrum. In addition, the NPRM proposes changes to the white spaces databases and changes for certifying, manufacturing and marketing white space devices and wireless microphones in the frequency bands at issue in this proceeding. In particular, the NPRM proposes rules to expand the location and frequency information in these databases so that they can be used to identify available frequencies for white space devices, including unlicensed wireless microphones, in the repurposed 600 MHz band, guard bands, and Channel 37.

2. The Commission's part 15 rules allow unlicensed devices to operate in the TV bands at locations where frequencies are not in use by licensed services. These devices, which are commonly referred to as TV white space (TVWS) devices, may be either fixed or personal/portable. The TV bands currently consist of six-megahertz channels designated 2 to 51 in four bands of frequencies in the VHF and UHF regions of the radio spectrum. TVWS devices are not permitted to operate on channel 37, which is allocated for the Radio Astronomy Service (RAS) and Land Mobile Service (the latter being limited to Wireless Medical Telemetry Service (WMTS), or on any other channel within 2.4 kilometers of protected radio observatories. To prevent harmful interference to broadcast television stations and other authorized users of these bands, TVWS devices obtain a list of available TV channels that may be used at their location from databases

administered by private entities selected by the Commission.

3. Certain entities may be issued licenses under subpart H of part 74 of the rules to operate low power auxiliary stations, including wireless microphones, in the TV bands. Because the operators of part 74 wireless microphones are licensed, they may register the times and locations of their operation in the TV bands databases to obtain interference protection from TVWS devices. The Commission also allows the operation of wireless microphones in the TV bands on an unlicensed basis under a waiver of the part 15 rules granted in the 2010. Operators of unlicensed wireless microphones are generally not permitted to register in the TV bands database, but parties operating large numbers of wireless microphones on an unlicensed basis at venues of events and productions/shows may register in the TV bands database if they meet certain criteria specified in the rules and obtain Commission approval.

4. In the *Incentive Auction R&O*, 79 FR 48442 (August 15, 2014), the Commission adopted rules to repurpose broadcast television spectrum in the UHF bands for licensed wireless services. Under these rules, full power and Class A broadcast licensees may participate in a reverse auction that will allow them to voluntarily relinquish some or all of their spectrum usage rights in exchange for financial compensation. A broadcast licensee that participates in the auction will have the option to turn in its license, move to a channel in the VHF band, or cease using its channel and share a channel with another licensee. The Commission will reorganize or repack the remaining full power and Class A television stations to clear the UHF band from channel 51 down. When the transition is completed, the TV bands will occupy a shorter frequency range than they do today and fewer channels may be available for TVWS and wireless microphone uses at any given location.

5. The Commission adopted a band plan for the repurposed 600 MHz spectrum (''600 MHz Band Plan'') in the *Incentive Auction R&O* that provides for a guard band between television spectrum and 600 MHz downlink services, a guard band between 600 MHz uplink and downlink services (a duplex gap), and guard bands between 600 MHz downlink services and channel 37. It decided to permit unlicensed devices, including unlicensed wireless microphones, to operate in the guard bands and duplex gap. The Commission also decided to permit unlicensed devices to operate on channel 37 and in spectrum reallocated and reassigned to new wireless services except in those areas where part 27 600 MHz Band wireless licensees commence operations. It stated that it planned to develop technical rules for unlicensed operation and to consider changes to the rules for TVWS devices in a separate proceeding.

A. Fixed and Personal/Portable White Space Devices

1. TV Bands

a. Permissible Frequencies of Operation

6. *Channels for white space device and microphone use.* Under the current rules, white space devices may not operate on the first two vacant TV channels above and below channel 37 to ensure that there is spectrum available for wireless microphones. In the *Incentive Auction R&O*, the Commission decided that it would no longer continue to designate up to two unused television channels in any area exclusively for wireless microphone operations. The Commission stated that in this proceeding we are initiating today, it would seek comment on ways it could update the rules for white spaces databases to provide for more immediate reservation of unused and available channels in the television bands to help ensure that licensed wireless microphone operators can obtain access to available television channels without receiving harmful interference from white space devices. It decided that it would continue to prohibit white space devices from operating on the first two vacant TV channels above and below channel 37 until such time as revised Commission rules are in effect to provide for more immediate interference protection. After that time, any available channels could be used by either wireless microphones or white space devices.

7. The Commission proposes to eliminate the prohibition on white space device operation on the first two vacant TV channels above and below channel 37 and make them available for use by white space devices when the rules proposes in this NPRM become effective. Specifically, the Commission proposes to increase the frequency at which white space devices must re-check the database, and limit the time required for a wireless microphone registration made in one white spaces database to appear in all other white spaces databases. The effect of these two proposals will ensure that a white space device ceases operation on a channel used by a wireless microphone within 30 minutes after a new microphone registration is entered into the database. The Commission seeks comment on these proposals.

8. In the *Incentive Auction R&O*, the Commission also stated that it expects there will be at least one channel not assigned to a television station in all areas of the United States at the end of the repacking process, and that it intends, after NPRM and an opportunity for public input, to designate one such channel in each area for shared use by white space devices and wireless microphones. The Commission plans to address the issue of a preserved white space channel in a separate proceeding. It is not proposing to make any changes to the white space rules with respect to a future preserved channel. Such a channel would simply appear in the white spaces database as vacant and would therefore be available for white space devices under the existing rules as well as any new or modified rules adopted in this proceeding.

9. *Operation of fixed devices on channels 3 and 4.* The current prohibition on fixed white space device operation on channels 3 and 4 may no longer be warranted. The Commission established this prohibition to protect TV interface devices and TV receivers from direct pickup interference on channels 3 and 4. The Commission did not have detailed data on the susceptibility of TV interface devices and TV receivers to direct pickup interference on channels 3 and 4, but decided to take a cautious approach due to the expected large number of TV interface devices with outputs on those channels. The number of these devices has declined significantly since 2008. The transition from analog to digital TV in 2009 spurred many consumers to replace their old analog TV receivers with digital receivers that have multiple inputs that allow the connection of external devices without requiring the use of a channel 3 or 4 input signal, including HDMI, component video and composite video inputs. Further, the price of new TV receivers has dropped significantly since that time, resulting in many more consumers replacing their old analog TV receivers. TV receivers also have been required to come equipped with digital TV tuners for a number of years, thus eliminating the need to use an external converter box to receive over-the-air signals. While we recognize that some consumers continue to use older analog TV sets with a converter box or other TV interface devices with a channel 3 or 4 output, we believe that number is significantly less than in 2008, and will continue to drop over time as older TV sets are replaced.

10. The Commission therefore proposes to eliminate the prohibition on

the use of channels 3 and 4 by fixed white space devices. This proposed action would provide an additional 12 MHz of contiguous spectrum for use by white space devices in areas where those channels are not used for authorized services. Limiting the use of these channels to fixed white space devices will reduce the likelihood of direct pickup interference to TV interface devices and TV receivers that continue use these frequencies, since a fixed white space device is less likely to be used in close proximity to a TV receiver than a portable device. The Commission seeks comment on this proposal. Specifically, it seeks comment on the extent to which consumers still use TV interface devices that operate on channels 3 and 4, *e.g.*, the estimated number and types of devices. The Commission also seeks comment on the susceptibility of TV interface devices and receivers to direct pickup interference on channels 3 and 4, particularly the signal levels at which such interference would occur as compared to the expected signal level from a nearby white space device. In addition, the Commission seeks comment on the extent to which white space device manufacturers would use TV channels 3 and 4 if they were available for fixed devices.

11. *Operation of personal/portable devices on channels 14–20 and below channel 14*. Operation of personal/portable white space devices is currently prohibited below TV channel 21. The Commission established a prohibition on personal/portable device operation on channels 14–20 to prevent possible interference to public safety and other operations in the PLMRS/CMRS that use channels in that range in certain cities and in other areas under waivers. It decided to prohibit the use of personal/portable devices on channels 14–20 nationwide since the devices could be easily transported anywhere.

12. The repurposing of spectrum for part 27 services will reduce the number of channels available for white space use, and relaxing the restrictions on the channels available for personal/portable devices could offset that reduction. We believe that it is appropriate to revisit the Commission's previous decisions to prohibit personal/portable device operation on channels 14–20 and below channel 14. Since the time the Commission made these decisions, it has designated multiple TV bands database administrators and has had extensive experience working with their databases. Based on that experience, the Commission has a high degree of confidence that the databases can reliably protect PLMRS/CMRS operations. The locations where the PLMRS/CMRS is used, both in eleven cities and in other areas where it is authorized under waiver, are already in the TV bands database since that information is used to protect those operations from fixed white space operations. Personal/portable devices rely on database access to determine their list of available channels, so they can protect the PLMRS/CMRS in the same manner as fixed devices.

13. Accordingly, the Commission proposes to remove the prohibition on personal/portable device operation on channels 14–20. This proposed action would make 42 megahertz of spectrum potentially available in locations where the spectrum is not used for the PLMRS/CMRS or other authorized services. The Commission seeks comment on the risk of interference to public safety and other PLRMS/CMRS based on the Commission's current technical rules for personal portable devices, *e.g.*, power limits and database access. It also seeks comment on any changes to the rules that would be required to minimize the risk of harmful interference if we were to allow operations on channels 14–20.

14. In addition, the Commission seeks comment on whether it should permit personal/portable devices to operate below channel 14. Allowing operation of personal/portable devices on channels 7–13 would make another 42 megahertz of spectrum potentially available for personal/portable devices. On which channels should we permit operation? Would manufacturers be interested in developing personal/portable devices that operate below channel 14 given the longer radio wavelengths at these lower frequencies?

b. Technical Rule Changes

(i) Fixed Device Operation on Adjacent Channels

15. Fixed white space devices, which can operate with a maximum power of four watts EIRP, are not permitted to operate on channels that are adjacent to occupied TV channels. They must always operate outside the defined service contours of adjacent channel TV stations by a minimum distance specified in the rules. Personal/portable devices, which can operate with a maximum power of 100 milliwatts EIRP, are generally required to operate outside the defined service contour of adjacent channel TV stations as well. However, personal/portable devices are permitted to operate within the service contour of adjacent channel TV stations if they reduce their power to 40 milliwatts EIRP. There is currently no corresponding provision in the rules that permits fixed devices to operate within the service contour of adjacent channel stations at reduced power. The requirement for fixed white space devices to avoid adjacent channel operation means that they may operate only at locations where there are three contiguous vacant TV channels, regardless of how low they reduce their operating power.

16. After the incentive auction and TV spectrum repacking, there will be fewer vacant TV channels available for white space devices. Therefore, the Commission expects that there will be fewer locations where three contiguous vacant channels exist, particularly in urban areas, thus limiting the locations where fixed devices may be used. The Commission proposes two changes to the current rules to provide fixed devices access to more vacant TV channels.

17. First, the Commission proposes to allow fixed devices to operate adjacent to occupied TV channels (*i.e.*, within their service contour), provided the operating power is reduced to 40 milliwatts EIRP. This is the same maximum power level that we permit for personal/portable devices that operate adjacent to occupied TV channels. This change would allow fixed devices to operate in locations where the spectrum is highly congested and available channels are not contiguous. The Commission also proposes to modify the table of separation distances in § 15.712(a)(2) to include co-channel separation distances for 40 milliwatt fixed devices. The current table of separation distances between fixed white space devices and co-channel television service contours was developed assuming a four watt EIRP device, so the separation distances are greater than necessary to protect TV service from a 40 milliwatt white space device. The methodology we will use for determining these distances and the proposed distances are discussed in the following paragraphs.

18. The Commission seeks comment on these proposals. In particular, it seeks comment on the appropriateness of making the rules for fixed and personal/portable white space devices consistent with respect to operation within an adjacent TV station's contour. The Commission also seeks comment on the usefulness of a 40 milliwatt power level for fixed devices and whether we could allow higher power levels without causing interference to adjacent TV stations. Parties that recommend higher power levels should submit technical justification (*e.g.*, analysis or test data) to support their recommendations.

19. Second, the Commission proposes to allow fixed devices to operate with a maximum power of four watts EIRP at locations where there are two contiguous vacant channels rather than three. When the Commission adopted the current requirement for three contiguous vacant channels, it stated that it would remain open to modifying this requirement if parties develop options that would permit operations on first adjacent channels that would not increase the potential for interference to television service and submit those for our consideration. This issue is revisited here because such operation will increase spectrum efficiency and the Commission believes, based on several studies, that operating in this manner will not increase the potential of interference to television reception. The Commission invites parties to submit information on such studies in response to this NPRM. The Commission further proposes that such operation would have to be within a six megahertz band centered on the boundary between the two vacant television channels, effectively reducing the frequency separation from six megahertz to three megahertz on each side of the white space channel. The Commission also proposes that the device would have to comply with all fixed white space requirements with respect to the six megahertz band in which it operates (*e.g.*, maximum conducted power, power spectral density and out-of-band emissions.) These changes would allow fixed devices to operate at the maximum power currently permitted under the rules in locations where they cannot operate under the current rules.

20. The Commission seeks comment on these proposals, particularly whether such operation would adequately protect television stations operating on adjacent channels. Commenters should indicate if they believe any rule changes are necessary to ensure protection of adjacent channel TV stations. For example, should we require slightly greater adjacent channel separation distances for fixed devices that operate with two vacant channels instead of three? If so, what are the appropriate distances?

(ii) Operation at Lower Power Levels

21. As proposed, there would be three power levels at which white space devices could operate: 40 milliwatts, 100 milliwatts and 4000 milliwatts EIRP. We note however, that the current table of separation distances in § 15.712(a)(2) was based on an EIRP of 4000 milliwatts which results in greater distance than necessary to protect TV reception from devices operating at 40 milliwatts or 100 milliwatts. By allowing shorter separation distances for devices operating at less than 4000 milliwatts EIRP, we can expand the locations at which they can operate.

22. In addition, we can provide even more flexibility for white space device users by defining intermediate power levels and corresponding separation distances. This will allow white space devices operating at less than the maximum permissible power to meet separation distances commensurate with their actual power and still protect over-the-air TV reception and other authorized services from harmful interference. As a result, white space devices, which must include transmit power control, would be able to operate in more locations with limited spectrum availability than available today. In crafting our proposal, we observe that the power increase from 40 milliwatts to 100 millwatts is 4 dB, and that the difference in power from 100 milliwatts to 4000 milliwatts is 16 dB. The Commission, therefore proposes a series of tables providing co- and adjacent channel separation distances from the TV contour based on intermediate power levels in uniform 4 dB steps for fixed devices. Specifically, it proposes to define separation distances for fixed devices at EIRP levels of 40 milliwatts, 100 milliwatts, 250 milliwatts, 625 milliwatts and 1600 milliwatts (*i.e.*,16 dBm, 20 dBm, 24 dBm, 28 dBm and 32 dBm, respectively) in addition to the current separation distances at 4000 milliwatts (36 dBm). The proposed separation distances and methodology for determining them are discussed below. The Commission also proposes that a device be required to indicate to the white space database the power at which it will operate when it requests a list of available channels. The Commission further proposes that when a device operates between two defined power levels, it must comply with the separation distances for the higher power level.

23. The current maximum fixed device power level of 4000 milliwatts EIRP is based on a maximum conducted power of one watt (1000 milliwatts) into an antenna with a gain of 6 dBi (a factor of four). If the antenna gain exceeds 6 dBi, the maximum conducted power must be reduced by the amount in dB that the gain exceeds 6 dBi. We propose similar requirements for fixed devices that operate at power levels less than 4000 milliwatts EIRP. Specifically, the Commission proposes to define a maximum conducted power limit for each EIRP level, which would be 6 dB lower than the EIRP. In addition, because the power spectral density (PSD) limit for fixed devices is based on the maximum conducted power limit, the Commission proposes to define a PSD limit for each of the proposed conducted power levels. The Commission further proposes to calculate the PSD limit using the same methodology described in the *White Spaces Third MO&O,* 77 FR 29236 (May 17, 2012). That is, the Commission will assume that the power of a device will be confined to a 5.5 megahertz band to allow a 250 kilohertz roll-off at the upper and lower edges of a channel to meet the adjacent channel emission limits. Consistent with the current rules, the Commission also proposes to require that the maximum conducted power and PSD limits for each EIRP level be reduced by the amount in dB that the maximum antenna gain exceeds 6 dBi. In addition, the Commission proposes that if a fixed device operates between these defined EIRP levels, the conducted power and PSD limits must be interpolated between the defined values shown.

24. The Commission seeks comment on the EIRP conducted power and PSD limits in proposals in paragraph 24 of the NPRM. In particular, it seeks comment on the usefulness of operation at the power levels proposed and whether there is a need to specify protection distances at additional power levels. The Commission also seeks comment on how the information on the power level and available channels should be communicated between the device and the database. For example, a fixed device could simply supply its geographic coordinates to the database, and the database could return a list of channels that indicates the maximum power at which the device could operate on each channel. Alternatively, the device could supply its locations and maximum power level and the database could return a list of available channels corresponding to operation at that location/power level combination. Are there other combinations of parameters for information exchange that would better suit such operation? What are the benefits and drawbacks of each alternative with respect to database operation and design and to equipment design? The Commission also seeks comment on the proposed PSD limits. Do these limits provide sufficient flexibility for device design and operation? Or would different limits be more appropriate? Commenters who advocate alternative limits and methodology should provide detailed technical analysis and justification to support their position.

(iii) White Space Devices in Rural Areas

25. The Commission seeks comment on a number of possible changes that could give more flexibility to operators of white space devices that would allow them to increase coverage and provide improved service in rural areas. For purposes of these proposals only, we use the term ''rural'' to refer to areas where there are numerous unused TV channels, which may be areas of low population density or areas that are merely under-served by broadcast services. In these cases, the potential for harmful interference from a white space device to a broadcasting station is significantly reduced. Specifically, the Commission seeks comment on whether to increase the limit on antenna height above ground for fixed devices in rural areas. The Commission also seeks comment on whether to allow higher power by fixed and personal/portable white space devices operating in rural areas. Finally, the Commission seeks comment on an appropriate definition of rural area for purposes of these proposals.

26. *Definition of rural area.* The part 15 rules do not define what constitutes a rural area. The Commission proposes to identify rural areas for white space devices as those where at least half of the TV channels are unused for broadcast services and available for white space use. At higher power, would fixed devices need to be located at a greater distance from a broadcast station contour, or would the fixed devices need to avoid operating on first, second or third adjacent channels? How might these factors affect the number and location of unused channels in identifying a rural area? The Commission seeks comment on the appropriateness of such a criterion or whether a different definition would better meet the needs of service providers. Because white space devices rely on a database to determine their list of available channels, the database would need to determine whether a fixed white space device is located in a rural area to allow such operation. Although the Commission believes that the white space databases already have the information needed to identify a rural area under the proposed criterion (*i.e.,* the identification of vacant TV channels at a given white space device location), the Commission seeks comment on what changes might be needed to implement this proposal, including the cost and programming complexity of such changes.

27. *Fixed device antenna height above ground.* The range at which a white space device could cause interference to authorized services increases as the antenna height increases. To limit this interference potential, the Commission established maximum height limits of 30 meters above ground level (AGL) and 250 meters HAAT for fixed white space device antennas. The Commission also established minimum required separation distances between white space devices and authorized services such as broadcast television that were determined based on the antenna height above ground and average terrain. The Commission adopted the 30-meter height above ground limit as a balance between increasing the white space device transmission range and the need to minimize the impact on licensed services. A higher antenna height above ground can improve signal propagation in suburban and urban areas by raising the antenna above obstacles such as trees and buildings. However, this increased signal propagation can also have a negative impact on spectrum sharing in congested areas where there are few available channels. The Commission stated that it could revisit the antenna height above ground limit in the future if experience with TV bands devices indicates they could operate at higher antenna heights without causing harmful interference.

28. A higher antenna height above ground could be beneficial in rural areas since an antenna could be mounted on a tower or other structure at a sufficient height to clear intervening obstacles such as trees and hills that would attenuate the transmitted signal. Increasing the antenna height could increase the maximum distance at which a signal can be received. There will generally be a significant number of available white space channels in rural areas, so there will not be the same concerns in those locations as in more congested areas about multiple users competing for spectrum. Since there are fewer authorized users of the spectrum in rural areas, there is a lower likelihood that an increased antenna height above ground will cause harmful interference. Accordingly, the Commission seeks comment on whether it should allow fixed white space device antennas at a height above ground of more than 30 meters in rural areas. If so, what is the maximum height that we should allow? What interference or spectrum sharing concerns would be raised by a higher antenna height above ground? Would we need to increase the minimum required separation distances to co-channel and adjacent channel television stations since the current distances assume a maximum antenna height above ground of 30 meters? If so, what are the appropriate separation distances? Similarly, should the Commission also consider increasing the HAAT limit for rural areas or keep that limit at 250 meters, but only allow a higher antenna height above ground level? What are the implications on interference distance from a higher HAAT limit along with a higher AGL limit?

29. *Power limit for fixed devices.* In adopting the four watt EIRP limit for fixed white space devices, the Commission recognized that there would be advantages to allowing operation of white space devices at higher power levels, such as reduced infrastructure costs and increased service range. However, the Commission decided not to allow the operation of fixed white space devices at power levels above four watts EIRP due to concerns about the increased risk of interference in congested areas that could make sharing spectrum between white space device users difficult. The Commission also stated that because it did not have experience with unlicensed wireless broadband operations in the TV bands, it would take a cautious approach in setting power limits to minimize the risk of harmful interference to authorized users of the TV bands. The Commission indicated that it would explore in a future proceeding whether higher powered unlicensed operation might be accommodated in the TV white spaces in rural areas.

30. The Commission seeks comment on whether it should allow fixed white space devices in rural areas to operate with up to ten watts EIRP, which could improve broadband service coverage in these areas. The Commission expects that equipment manufacturers can achieve this higher EIRP level by using higher gain antennas (10 dBi rather than 6 dBi), with no increase in the one watt conducted power level currently permitted. The Commission believes that requiring a higher gain antenna to achieve the higher EIRP as opposed to a higher transmitter power is appropriate for several reasons. First, it will result in more efficient spectrum use because the power from a higher gain antenna will be concentrated in a narrower beamwidth, thus reducing the likelihood of interference to authorized services and to other white space device users. Also, the Commission believes that use of fixed devices at these higher power levels would be limited to point-to-point type operations as it is unlikely that lower power personal/portable devices would be able to communicate over the increased distances.

31. The Commission seeks comment on the appropriateness of a ten watt power level and the degree to which it could help rural broadband operators improve or expand their service offerings to additional areas. What is the trade-off in terms of cost and system complexity of using a single high power fixed station as opposed to several lower power stations? The Commission also seeks comment on whether it should allow higher transmitter output power (*i.e.,* greater than one watt) as an alternative to, or in addition to, higher gain antennas. In addition, if we were to adopt rules for higher power, should we provide for intermediate levels between 4 and 10 watts EIRP? If so, what are the appropriate levels? The Commission further seeks comment on the impact of these proposed changes on authorized services in the TV bands. It recognizes that allowing a higher power level for white space devices will require greater separation distances from co-channel and adjacent channel TV stations. Would the methodology described below for determining such separation distances be appropriate for higher power white space devices in rural areas? Would we need to increase the minimum separation distance from protected services such as licensed wireless microphones, registered receive sites, and the PLMRS in addition to full power and Class A television stations?

32. *Power limit for personal/portable devices.* The Commission established a lower power limit for personal/portable devices (100 milliwatts EIRP) than for fixed devices (4 watts EIRP). The Commission adopted this lower limit because it found that personal/portable devices generally pose a greater risk of harmful interference to authorized operations than fixed devices because portable devices will change locations, making identification of both unused TV frequencies and the devices themselves, if harmful interference occurs, more complex and difficult. It further stated that the significant distances at which harmful interference could occur from a personal/portable device operating at greater than 100 milliwatts would make it very difficult to identify a device that is the source of harmful interference.

33. Higher power limits for personal/portable devices in rural areas could benefit the public by enabling applications that are limited or precluded by the current rules, such as mobile communications and vehicle tracking. We recognize the Commission's previous concerns with higher power limits for personal/portable devices. However, we believe that personal/portable devices may be able to operate at higher power levels in certain limited situations without a high risk of harmful interference to authorized services. Specifically, they may be able to operate at higher power in rural areas where there are a large number of TV channels available for white space use. In that situation, the risk of harmful interference to services operating in the TV bands is lower. Further, the rules contain detailed requirements for Mode II personal/portable devices that are designed to prevent harmful interference to authorized services. Specifically, they must: (1) Be capable of determining their position to within 50 meters; (2) re-check their position every 60 seconds; (3) access a database to determine the list of available channels at their location; and (4) re-check the database whenever they move at least 100 meters from their last location.

34. The Commission seeks comment on whether it should permit personal/portable devices to operate at higher power in rural areas. If so, what should be the maximum power at which they can operate? Should we limit higher power personal/portable devices to certain types of applications? If so, what applications? If we were to allow personal/portable devices to operate at higher power, would we need to adopt any additional requirements to prevent harmful interference to authorized services? If so, what requirements? For example, should personal/portable devices be required to comply with larger separation distances from authorized services than fixed devices operating at comparable power levels?

(iv) Channel Bonding and Out-of-Band Emission Limits

35. White space devices must comply with a three part out-of-band emission limit. First, they must comply with a power limit (conducted for fixed devices and EIRP for portable devices) in the television channels immediately adjacent to the channel in which the device operates. Second, they must comply with the § 15.209 radiated emission limits at frequencies beyond the television channels immediately adjacent to the channel in which the white space device is operating. Third, they must comply with stringent out-of-band emission limits on channels 36 through 38.

36. The Commission notes that the current out-of-band emission rules were written with the assumption that a white space device would transmit on a single six megahertz TV channel and meet the appropriate out-of-band emission limits at all frequencies outside of this single channel. However, a white space device could be designed to use two or more channels simultaneously to increase its transmission bandwidth and maximum data rate. A device could use multiple non-contiguous channels, *i.e.* channel aggregation, or could use multiple contiguous channels, *i.e.* channel bonding. There is no prohibition in the rules on the use of multiple channels by a white space device. In fact, the rules already implicitly allow the use of multiple channels by a single device since they specify the maximum power limits per six megahertz of bandwidth, indicating that a device may use multiple six megahertz channels. However, because the rules do not consider cases where a white space device transmits on multiple channels simultaneously, we believe that the current out-of-band emission rules in § 15.709(c) could be modified so that users could better make use of the efficiencies associated with channel aggregation and channel bonding. Channel aggregation and channel bonding will allow the development of devices that transmit at higher data rates, thus making higher speed equipment available to consumers.

37. The Commission, therefore, proposes several rule changes with respect to channel bonding. The Commission proposes to modify § 15.709(c)(1) to specify that the adjacent channel emissions limits do not apply within an adjacent channel that is being used by the same white space device, since in such cases there would be no TV station or other authorized service to protect on the adjacent channel; that is, to operate on two adjacent channels, a device would need to receive a message from a white space database that both channels are available at its location. Instead, the Commission proposes to apply these limits within the six megahertz bands immediately above and below the edges of the band of contiguous channels used by the white space device. The Commission also proposes to require that a device must meet the § 15.209 limits at frequencies more than six megahertz above and below the edges of the highest and lowest channels used in the device. The Commission further proposes to apply these requirements to fixed devices that operate centered on the boundary of two channels as proposed above, since that is a form of channel bonding. The Commission seeks comment on these proposals. In particular, it seeks comment on whether the white space databases will need to make any adjustments to accommodate channel bonding as proposed. Would

programming changes be necessary or should the logic to bond channels reside solely within a device based on the list of available channels obtained from the white space database? How easily can existing devices accommodate these changes or would new devices need to be designed?

38. With respect to channel aggregation, the Commission proposes to modify § 15.709(c)(2) to indicate that when a white space device transmits on multiple non-contiguous channels simultaneously, it must comply with the adjacent channel emission limits in the six megahertz bands above and below each of the single channels or channel groups used by the white space device. In such cases, the white space device would have to comply with the § 15.209 limits at frequencies outside of the channels used by the device and the six megahertz bands adjacent to the channels used by the device. The Commission seeks comment on this proposal.

39. *Adjacent channel emission levels.* In addition to our proposals to modify the adjacent channel emission rules to allow for channel bonding and aggregation, we are proposing to add emission limits for fixed devices operating at the proposed new power levels that are less than four watts EIRP. The Commission further proposes to correct the method of specifying the emission limits for fixed devices using a high gain (greater than 6 dBi) antenna.

40. In the *White Spaces Third MO&O,* the Commission decided to set the adjacent channel emission limit, measured in a 100 kHz bandwidth, as 72.8 dB below the maximum permitted power measured in a 6 MHz bandwidth. This results in an adjacent channel conducted emission limit of −42.8 dBm for the maximum permissible one watt (30 dBm) conducted power for fixed devices. Because the Commission is now proposing to define additional conducted power levels for fixed devices that are less than 30 dBm, we are proposing adjacent channel emission limits corresponding to these lower power levels. These proposed limits, shown in the table in paragraph 59 of the NPRM, are calculated using the methodology in the *White Spaces Third MO&O.* The Commission proposes that a device that operates between two defined power levels must comply with the limit for the higher power level.

41. The Commission seeks comment on the appropriateness of these limits. It recognizes that we could simply adopt the −42.8 dBm level for all power levels, but by providing flexibility based on power, our rules will provide for lower power white space devices to operate closer to the TV contours than higher power devices.

42. Similarly, the rules in § 15.709(c)(1)(i) do not compensate for fixed devices with antenna gains greater than 6 dBi where the device must operate by reducing its maximum conducted power by the amount in dB that the antenna gain exceeds 6 dBi. In such situations, the adjacent channel emission limits also need to be reduced because they are calculated relative to the maximum conducted power (*i.e.,* 72.8 dB lower). The Commission therefore proposes to modify § 15.709(c)(1)(i) to require that the adjacent channel emission limits for fixed devices be reduced in the same manner as the in-band power, *i.e.,* by the amount in dB that the antenna gain exceeds 6 dBi. This approach is consistent with the methodology used to determine compliance with the power spectral density limit for fixed devices. The Commission seeks comment on this proposal.

43. In light of the proposals above, the Commission seeks comment on whether it should relax the current adjacent channel emission limits. Are these limits difficult to meet and does the necessary filtering increase the cost of equipment? Commenters advocating for less stringent adjacent channel emission limits are requested to provide proposals detailing different levels along with analysis showing the effect of TV reception, the potential interference to other authorized services in the band and any effect such changes would have on the required separation distance between white space devices and adjacent channel TV stations. For example, to compensate for less stringent out-of-band requirements we could increase the adjacent channel separation distances to TV station contours. What are the benefits of adopting such rules? And what would be the effect on the white space databases? Would devices need to transmit information regarding their out-of-band emission levels to the database to be used when calculating the list of available channels? Or could information regarding the capabilities of various devices reside in the database? How would such a scheme work? Another option would be to provide a range of adjacent channel emission limits with corresponding separation distances. The Commission seeks comment on this option and what benefits such flexibility would add. Or would the added complexity introduced to both devices and the database negates any potential benefits? Finally, the Commission seeks comment on the effect that less stringent adjacent channel emission limits would have on services and uses where there are no adjacent channel separation requirements, such as on wireless microphones or on TV stations adjacent to 40 milliwatt white space devices.

(v) Calculating the Separation Distances From a TV Station Contour

44. The rules require that white space devices protect defined service contours of analog and digital full service and low power television stations. These contours are calculated using the methodology in § 73.684 of the rules and the F(50,50) and F(50,90) curves contained in § 73.699. Under the current rules, fixed white space devices must operate outside the contours of co-channel and adjacent channel TV stations at the distances specified in the table in § 15.712(a)(2). This table provides co-channel and adjacent channel separation distances for nine ranges of fixed device HAAT, up to a maximum of 250 meters. Personal/portable devices that operate with an EIRP greater than 40 milliwatts, up to the maximum of 100 milliwatts, must comply with the co-channel and adjacent channel separation distances at the lowest HAAT in the table (*i.e.,* less than 3 meters). Personal/portable devices operating at 40 milliwatts or less only need to comply with the co-channel separation distance at the lowest HAAT listed in the table.

45. The Commission described the methodology it used to determine the table of separation distances in the *White Spaces Third MO&O.* Specifically, the Commission calculated the distances assuming a fixed white space device with an EIRP of four watts. It used a D/U signal ratio of 23 dB to protect co-channel TV reception, and −33 dB to protect adjacent channel TV reception. The Commission assumed that a TV receive antenna within a TV station's protected service contour would have a front to back ratio of 14 dB as specified in the DTV planning factors of OET Bulletin 69. Using these factors, it calculated the minimum required separation distances that a white space device must operate outside a TV stations' protected contour using the F(50,10) and F(50,50) curves over the range of antenna heights and distances at which these curves are defined. For HAAT values below 30 meters and for contour distances of less than 1.5 kilometers where the F(50,50) and F(50,10) curves are not defined, the Commission used the TM 91–1 propagation model to calculate the required separation distances.

46. The Commission is proposing to amend the table of separation distances in § 15.712(a)(2) to reflect the proposals above that would allow fixed device operation at a range of power levels below four watts EIRP. Requiring shorter separation distances for fixed white space devices with power levels below four watts will permit them to operate in more locations than the current rules allow, *i.e.,* closer to a television station service contour, since the current separation distances were based on the assumption that a fixed device always operates at the maximum power level. In addition, since the separation distances for personal/portable devices were also based on an EIRP of four watts, they are greater than necessary since personal/portable devices may operate with a maximum EIRP of 100 milliwatts, or 40 milliwatts if they are on a channel adjacent to an occupied channel. Because we are calculating separation distances for fixed devices at 40 milliwatts and 100 milliwatts EIRP, we propose to apply those separation distances, based on the lowest antenna HAAT, to personal/portable devices. This proposal will increase the number of locations where personal/portable devices may operate.

47. The Commission notes that the table of separation distances will increase in size due to the inclusion of additional power levels and therefore propose to split the table into two: one for co-channel and the other for adjacent channel separation distances. It also proposes to add an entry to show which separation distances apply to personal/portable devices, see table in paragraph 66 of the NPRM. The proposed co-channel separation distance table is as follows:

48. The proposed adjacent channel separation distances are shown in paragraph 67 of the NPRM. There is no entry for 40 milliwatt (16 dBm) devices because fixed and personal/portable devices operating at this power level would not have to meet adjacent channel separation distance requirements. This proposed table would correct an error in the current rules for the separation distances at the four watt power level. The Commission determined that the current separation distances were inadvertently calculated without considering the 14 dB receive antenna front-to-back ratio that the Commission previously stated it would use in determining these distances. Therefore, they are larger than they would be if the receive antenna directivity were taken into account. All of the distances in the following table were calculated using the 14 dB receive antenna front-to-back ratio.

49. The Commission seeks comment on this proposal. In particular, it seeks comment on whether these separation distances will provide adequate protection to co-channel and adjacent channel TV stations at the power levels and antenna HAATs listed. Parties that suggest changes to these distances should provide a technical analysis explaining their rationale. The Commission also seeks comment on the validity of the calculated prediction distances at low power levels (*e.g.,* 40 milliwatts) and high HAAT. Is a 40 milliwatt white space device capable of causing interference to co-channel television stations at the calculated distances (over 12 kilometers at the maximum HAAT)? Do we need to consider the HAAT of low power white space devices?

50. In addition, we note that some parties have informally advised the Commission that they believe the Commission's current table of separation distances is overly conservative in some cases, and therefore limits the amount of white space spectrum available for unlicensed devices. The Commission therefore seeks comment on whether it should make additional rule changes with respect to the following issues.

51. Alternative propagation models for calculating interference. As discussed above, the Commission requires the use of the propagation curves in the rules for calculating the protected service contours of TV stations. Digital TV service contours are calculated using the F(50,90) curves, and analog TV service contours are calculated using the F(50,50) curves. Additionally, the table of separation distances between TV station service contours and white space devices was calculated using the F(50,10) and F(50,50) curves over the range where they are defined. Some parties have suggested that the Commission use other propagation models such as the Longley-Rice methodology or the Hata models to determine where white space devices could operate without causing interference to TV reception.

52. In seeking comment on alternative propagation models, we note that we are not proposing any changes to the method of calculating the protected service contours of TV stations using the F(50,90) and F(50,50) propagation curves. This is the method specified in the part 73 rules for calculating TV service contours, and we believe it is appropriate to require unlicensed white space devices to follow the same method for determining protected TV contours. In addition, the Commission do not believe the use of the Longley-Rice methodology would be appropriate for determining whether a white space device would cause interference to TV reception as it is computationally intensive and would significantly slow the determination of available TV channels by the white spaces databases.

53. With regard to the calculation of distances in the separation table, the Commission used a combination of its own propagation curves and the TM 91–1 to calculate separation the distances. It recognizes that this may not be the only appropriate methodology for calculating separation distances. We therefore seek comment on whether the Commission should consider using other propagation models that could give a more accurate indication as to whether interference is likely occur to TV reception. For example, are the Hata models appropriate for making these calculations? Are there other models that could be used? Could the separation distances calculated using other models provide a high degree of confidence that interference to TV would not occur? How would the separation distances obtained with an alternative model differ from those calculated with the methodology previously used by the Commission? Would the differences in these distances increase the amount of available white space, and if so, by how much?

54. *Directional antenna use by white space devices.* The Commission considered the directivity of TV receive antennas in developing the table of separation distances for white space devices and assumed a 14 dB front-to-back ratio. Because a TV receive antenna located just inside the protected contour of a TV station would be pointed toward the TV station, it would therefore be pointed away from a white space device located just outside the contour. However, the Commission did not consider the directivity of a white space transmit antenna in developing the table of separation distances and assumed an omnidirectional transmit antenna with a transmit power of four watts EIRP. The Commission stated that it was desirable to minimize the complexity for compliance while providing assurance that TV stations would be adequately protected. Likewise, when the Commission modified the table of protection distances in the *White Spaces Third MO&O* to allow white space device operation at higher antenna HAAT, it did not consider the directivity of the white space device transmit antenna.

55. The directional pattern of a fixed white space device transmit antenna could affect the identification of available channels. In the case where

the transmit antenna points away from a TV station that the white space device must protect, the effect would be that the white space device has a lower EIRP in the direction of the TV station. Under such situations it may be possible to reduce the required separation distance between the white space device and the protected contour of the co-channel and adjacent channel TV stations. This change could increase the number of locations where a fixed device could operate. However, there are a number of factors that have to be considered to ensure that white space devices provide adequate protection to TV stations. For example, antenna pattern information for fixed white space devices, including the orientation of the antenna as installed in the field would be needed. This information would then have to be stored in some format in the white spaces databases. The Commission would also have to develop appropriate protection criteria for a fixed white space device that uses a directional antenna. For example, we may need to specify the minimum arc size over which the power must be reduced in the direction of a protected TV station, since reduced power over a very narrow arc may not provide adequate protection.

56. Accordingly, the Commission seeks comment on whether it should modify the rules to consider the directional antenna pattern for fixed space devices. If so, how can we assure the accuracy of antenna pattern information? Should we require the database to store detailed information, such as the antenna gain at one degree intervals, or could we define several simpler generic patterns that approximate commonly used antennas? Should the database be responsible for storing various antenna patterns or should they be transmitted to the databases by the device at power up the first time it requests a channel list? How would we specify the appropriate protection criteria for white space devices using directional antennas? For example, could the protection distances proposed above for multiple power levels be used in conjunction with directional antenna information to protect TV reception? What other criteria would we need to specify?

(vi) Location Accuracy

57. A fixed or Mode II personal/portable device must be able to determine its position and provide that information to the white spaces database, which then determines whether the device meets the minimum required separation distances from protected services. The rules currently require that a fixed or Mode II personal/portable device incorporate a geo-location capability that can determine its geographic coordinates to within ±50 meters. GPS is capable of determining coordinates to this level of accuracy, but there may be circumstances where it is not possible to receive a GPS signal, such as indoors or at outdoor locations where there are obstacles such as buildings and trees. The Commission seeks comment on whether there are other location methods besides GPS that can determine a white space device's location to within ±50 meters. If so, what are these methods? The Commission also seeks comment on whether devices need to determine their position with this level of accuracy to protect authorized services.

58. In addition, the Commission seeks comment on whether we should allow white space devices to use geo-location methods that are less accurate than the current rules require, provided they provide the same level of protection to authorized services. If so, what level of accuracy should be required? How could we assure that devices with a lower level of geo-location accuracy do not cause interference to authorized services? Could we require white space devices to operate at greater distances from authorized services to offset the increased uncertainty in a device's location? If so, should we require all white space devices to meet increased separation distances, or only those with less accurate geo-location capabilities? If we allow only some devices to use a less accurate geo-location method, how could the white space databases take into account a device's geo-location accuracy in determining the list of available channels? The accuracy of some geo-location technologies, such as GPS, is well established, but this may not be the case for geo-location technologies, some of which may be proprietary, that manufacturers wish to use for white space devices. How should the location accuracy of a device be tested? Should manufacturers be required to certify the accuracy of the location technology incorporated into a device as part of the equipment certification process? Are there any other approaches that would allow white space devices to incorporate less accurate geo-location capabilities while still protecting authorized services?

2. 600 MHz Guard Bands

59. The 600 MHz Band includes a guard band between the wireless downlink services band and the TV band that will vary in size and frequency depending on the amount of spectrum recovered in the auction. There are three possibilities for the size of this guard band: 11 megahertz, nine megahertz and seven megahertz. However, if exactly 84 megahertz of spectrum is recovered in the auction, channel 37 plus the three megahertz guard band that protects the WMTS and RAS on channel 37 will serve as the guard band between the wireless downlink services band and TV band. Therefore, there would not be a separate guard band between the TV band and the wireless downlink services band that could be made available for unlicensed use as there would be under all other spectrum recovery scenarios.

60. The Spectrum Act states that the Commission may permit unlicensed use of the guard bands, and stipulates that (a) unlicensed use shall rely on a database or subsequent methodology as determined by the Commission, and (b) the Commission may not permit any use of a guard band that the Commission determines would cause harmful interference to licensed services. The term ''guard band'' includes the duplex gap, and thus the Spectrum Act's requirements discussed here apply equally to the duplex gap. Fixed and personal/portable white space devices clearly satisfy the Act's stipulation that ''unlicensed use rely on a database'' since our rules already require that these devices access a database to identify vacant TV channels in their area that meet the interference avoidance requirements of our rules, and they may only operate on the vacant channels that the database identifies. This Commission is proposing in this NPRM to expand the information in the white space databases to include 600 MHz Band services that will be entitled to interference protection. The Commission's part 15 rules already require that unlicensed devices not cause harmful interference to and must accept interference from authorized users. In this NPRM, the Commission proposes technical and operational rules for white space devices in these bands that will satisfy the requirements of both the Spectrum Act and our rules.

61. The Commission proposes to allow fixed and personal/portable devices to operate in the guard bands and duplex gap. The current white space rules provide for two types of personal/portable devices. Mode II devices, like fixed devices, incorporate geo-location and database access capabilities which facilitate their ability to meet the required separation distances at their operating location, while Mode I devices do not. Instead, Mode I devices must obtain a list of available operating channels from a fixed or Mode II personal/portable white

space device that is within their transmission range and may only operate so long as they can receive a controlling signal from the fixed or Mode II device. Because Mode I devices are limited to a maximum EIRP of 100 milliwatts, or 40 milliwatts EIRP if they are adjacent to an occupied TV channel, they must operate relatively close to the device that provides the list of available channels. Thus, the actual location of a Mode I device is different from the device providing it a list of available channels. The Commission seeks comment from parties contemplating use of Mode I devices on the types of functions and applications they envision for these devices, and the typical and maximum operating range envisioned for these devices. It also seeks comment on any studies that address the interference potential of Mode I devices. The Commission further seeks comment on whether it should limit operation in these bands to fixed and Mode II devices only to ensure protection to authorized services in these bands. Alternatively, should we also allow Mode I devices to operate in these bands, but increase the separation distances to offset the uncertainty in the devices' locations? In addition, the Commission seeks comment on whether any limitations on the types of devices in the duplex gap would be necessary after the 39 month transition period when all television stations are moved from the spectrum that is designated as the duplex gap. The Commission asks commenters to address the effect that any limitations on the permissible types of devices in these bands may have on the development of white space services and applications.

62. A white space device operating in a guard band would have to protect two different authorized services on frequencies immediately adjacent to the guard band. Broadcast television will operate in the lower adjacent spectrum, and licensed wireless downlink services will operate in the upper adjacent spectrum. The current rules permit operation of personal/portable white space devices on a channel that is immediately adjacent to an occupied TV channel, provided the device power is reduced to 40 milliwatts. In the NPRM, the Commission is proposing to also allow fixed devices to operate on a channel immediately adjacent to an occupied TV channel at the same 40 milliwatt power level, and it is proposing to allow fixed devices to operate at 4 watts EIRP three megahertz away from an occupied TV channel. However, the Commission does not currently have rules for white space devices that address operation on a channel immediately adjacent to wireless downlink services. Therefore, the Commission must develop rules to protect wireless downlink services adjacent to the guard bands, that is, protecting the ability of handsets to receive signals from a base station. The analysis discussed applies equally to the duplex gap because white space devices operating in the duplex gap must also protect wireless downlink services in adjacent frequency bands. The Commission proposes to protect wireless handsets by limiting the power of white space devices in the guard bands and duplex gap, and by requiring a buffer between the edge of the channel used by the white space device and wireless downlink services. The proposed approach ensures against harmful interference to licensed services and promotes the public interest and benefits inherent in maximizing spectrum use.

63. The Commission considers separately the guard band sizes under each of the spectrum recovery scenarios. In each case, we assume that the white space devices could be either fixed or personal/portable, that they will transmit over a six megahertz wide bandwidth, that they could be operating at 40 milliwatts immediately adjacent to an occupied TV channel, and that their operation will be controlled through use of a database. The power limits and frequency separation needed to protect part 27 wireless services will alter the assumptions for white space devices' power limits and bandwidth in each case and, ultimately, how white space devices could use the guard bands. Based on our preliminary analysis, discussed below, we also assume a three megahertz frequency separation between the white space devices and the handset receive band to offset a worst case interference distance of less than seven meters. Our preliminary analysis is based on conservative assumptions, and intended as a starting point for purposes of developing a record on these issues. There are numerous ways to conduct interference analyses and each depends on a number of assumptions, such as filter characteristics, the propagation model and miscellaneous losses (*e.g.,* body loss, polarization mismatch, etc.). In addition, the Commission notes that there is a lack of real world testing between white space transmitters and LTE receivers, and we invite manufacturers and other interested parties to submit data and test results to the record in this proceeding. Nevertheless, we believe that under reasonable conditions white space devices can operate in the duplex gap and guard bands without causing harmful interference to LTE receivers.

64. In the Incentive Auction proceeding, Qualcomm has submitted analyses purportedly showing that unlicensed use in the guard bands and duplex gap is not feasible without extremely large frequency separations from licensed services and Broadcom has submitted analyses to the contrary. Both parties' analyses rely on the 3GPP industry standards which define the onset of blocking interference at more than a five percent degradation in throughput. While the Commission does not go into the merits of these analyses here, our preliminary analysis also relies on the 3GPP standard for frequencies closest to the 600 MHz band as a starting point. However, the Commission notes that these standards contain minimum specifications and equipment used by wireless carriers may significantly exceed these minimums.

65. This standard sets a floor of −97 dBm for LTE receiver sensitivity and an adjacent channel selectivity of 33 dB. The Commission believes it is reasonable to assume at least 25 dB of additional loss over any path loss to include an additional 10 dB for adjacent channel selectivity plus an additional 15 dB of loss due to a combination of obstructions, body loss and antenna polarization mismatch, etc. The Commission further assumes a minimum of three megahertz frequency separation between white space devices and LTE receivers, resulting in a seven dB pass band filter attenuation. The Commission calculated the required separation distances using the TM 91–1 model. In doing so, it assumes a white space device with a maximum EIRP of 40 milliwatts and an antenna height of three meters, which is the lowest antenna height the part 15 rules specify for white space devices. The Commission also assumes a 1.5 meter LTE handset height, which we believe is representative of typical wireless handset use. Based on these assumptions, our calculations show a worst case interference distance of less than seven meters.

66. While the Commission recognizes there may be concerns about the potential for interference to wireless handsets at seven meters, we emphasize that our preliminary analysis is a static, worst case analysis that does not consider many other factors that would tend to reduce this distance. For example, it does not take into account the behavior of deployed networks which manage operating channels and

handset power in noisy conditions to ensure the best possible connection, nor does it take into account the probabilistic nature of the conditions that lead to an interference situation. For example, if an LTE handset is operating at the edge of coverage on a frequency at the edge of the band closest to the guard band in very close proximity to a white space device, the white space device, which must incorporate transmit power control, will limit its operating power to the minimum necessary for successful communication, so its power will often be less than the maximum on which we based our preliminary analysis. Additionally analyses that are based on the onset of blocking may not rise to the threshold of harmful interference if one considers transmission protocols and modulation schemes which are designed to facilitate operations when conditions are less than ideal by incorporating coding, bit interleaving, and retransmission events when necessary. Finally, the Commission notes that based on device and spectrum usage evolution, manufacturers have incorporated a range of unlicensed and licensed bands into devices and we expect that this will be the case with white space devices too. Given that there is some time prior to networks being deployed, we expect manufacturers to improve filter technology and designs to ensure a minimum potential for harmful interference.

67. In the guard band scenarios discussed, the Commission is proposing to allow white space devices to generally operate in the guard bands and the duplex gap at a maximum power level of 40 milliwatts and a three megahertz frequency separation from the handset receive band. The Commission seeks comment on this proposal. The Commission invites comment on the assumptions we make for wireless broadband service to the public by both licensed services and unlicensed devices. Parties that disagree are requested to provide their own assumptions, including what frequency separations are needed to protect wireless services from harmful interference, along with justification and analysis. The Commission also ask those parties who advocate against use of the guard bands for unlicensed use to provide details on what services they believe could operate there and under what operating conditions, so that valuable spectrum does not lay fallow. Parties should address how white space use in each scenario below would satisfy the Spectrum Act's requirement that no harmful interference is caused to licensed services.

68. *Eleven megahertz guard band.* Fixed and personal/portable white space devices could operate in the lower six megahertz portion of the guard band, adjacent to broadcast TV spectrum, leaving a five megahertz separation to wireless downlink services at the upper portion of the band. In this case, under the existing white space rules, the white space devices could operate at 40 milliwatts adjacent to an operating TV station and 100 milliwatts if the adjacent station is vacant. The Commission proposes that white space devices be permitted to operate at 40 milliwatts so long as it maintains a three megahertz separation distance from the lower edge of the band where handsets will receive. Is the 40 milliwatt power level useful for unlicensed devices? Should we permit operation up to 100 milliwatts if the white space device can maintain 4 or 5 megahertz separation from the handset receive band and satisfy the conditions for protecting TV reception as well as the necessary distance separation from adjacent base stations? Would a different power level be used?

69. *Nine megahertz guard band.* The Commission proposes that fixed and personal/portable white space devices could operate at 40 milliwatts in the lower six megahertz portion of the guard band adjacent to broadcast TV spectrum, leaving three megahertz separation to wireless services. The Commission believes this would adequately protect handsets from harmful interference while providing an opportunity for unlicensed devices to operate. The Commission seeks comment on this proposal and asks if there are other operating scenarios for the nine megahertz guard band that could be adopted to provide for unlicensed device use while protecting wireless handsets.

70. *Seven megahertz guard band.* In this case, if fixed and personal/portable white space devices operated adjacent to the broadcast TV band at the lower end of the guard band, there would be only one megahertz separation to wireless downlink services at the upper end of the band. Under this situation, could we provide for 40 milliwatt white space device operation? Alternatively, could white space devices operate at reduced power with only one megahertz of separation from broadband downlinks and still protect those operations? What power level and separation distance would provide for such operation? Another option is to restrict white space devices to a four megahertz bandwidth to maintain three megahertz separation from broadband downlinks. Is the current white space equipment capable of such operation? Is there a market for operating in this manner as it would necessitate slower data rates? What parameters in terms of power and separation distance would be required to ensure operation of all services? The Commission seeks comment on the appropriate power limits and frequency separations for white space devices to protect both TV and wireless services in this case.

71. *Three megahertz plus channel 37.* In the case where 84 megahertz of spectrum is recovered in the auction, the guard band between wireless downlink services and TV spectrum will consist of channel 37 plus a three megahertz guard band. The purpose of the three megahertz guard band is primarily to protect the WMTS and RAS on channel 37 from interference from wireless downlink services, but it also would protect wireless downlink services from harmful interference from white space devices operating on channel 37. If we determine that less than three megahertz separation is needed to protect part 27 services, could fixed or personal/portable devices make use of any portion of this three megahertz band? The Commission seeks comment on whether any types of low power, narrowband devices could use this guard band without causing harmful interference to licensed services in the adjacent bands. Is so, what types of devices and at what power levels and bandwidths?

3. 600 MHz Duplex Gap

a. Types of Permitted Operations

72. The 600 MHz Band includes a duplex gap of 11 megahertz between the wireless uplink and downlink services bands to prevent harmful interference between them. The frequency range of this duplex gap will depend on the outcome of the incentive auction, but the size of the band will be the same nationwide, regardless of whether there is any market variation in the amount of spectrum recovered in certain areas. Wireless downlink services will operate in the lower adjacent spectrum to the duplex gap, and wireless uplink services will operate in the upper adjacent spectrum to the duplex gap. In the *Incentive Auction R&O,* the Commission concluded that the public interest would be served by allowing broadcasters and cable programming networks to use wireless microphones on a licensed basis in a portion of the duplex gap and to obtain interference protection from unlicensed devices at specified times and locations, on an as-

needed basis. The Commission decided that it would in a future proceeding examine how best to provide access to a portion of the duplex gap by licensed wireless microphone users, while also ensuring that unlicensed users of the duplex gap can make use of this spectrum to provide broadband services. It anticipated that the duplex gap could be partitioned such that six megahertz would be available for unlicensed broadband devices to operate under the existing white space rules for 40 milliwatt personal/portable devices, and four megahertz adjacent to the wireless downlink services band would be available for licensed wireless microphone operations. This approach would leave one megahertz available for use as a buffer to protect licensed wireless services.

73. There are several different ways to divide the duplex gap to accommodate wireless microphones and white space devices, although there are trade-offs with each one. As an initial proposal, the Commission proposes to allow unlicensed operations, including both fixed and personal/portable white space devices and unlicensed microphones, to operate in the six megahertz band segment at the upper end of the duplex gap. It also proposes to allow licensed wireless microphones to operate in the four megahertz band segment immediately below this six megahertz segment. The Commission further proposes to use the remaining portion of the duplex gap spectrum to provide a one megahertz frequency separation between licensed wireless microphones and wireless downlinks in the spectrum below the duplex gap, thereby providing an additional margin of interference protection to mobile handsets. Thus, licensed wireless microphones would be able to operate in the band between one and five megahertz above the lower end of the duplex gap, and unlicensed devices, including wireless microphones, would be able to operate in the band from five to eleven megahertz above the lower end of the duplex gap.

74. The Commission believes that providing a six megahertz band for unlicensed devices is appropriate since that is the minimum size that many parties indicated is useful for unlicensed uses, and it is consistent with the current fixed and personal/portable white space rules. Additionally, it believes that a four megahertz segment of the duplex gap will be useful for licensed wireless microphones that are used on short NPRM since it will be available nationwide. Manufacturers have indicated that as many as 16 wireless microphones can operate in a six megahertz channel, and while we are proposing a smaller channel size here, manufacturers should still be able to get a substantial number of microphones to operate in it.

75. The Commission is not proposing to provide a guard band between licensed wireless microphones and unlicensed white space devices, since white space devices must comply with low emission limits outside their channel of operation. Also, wireless microphones that operate in this spectrum use narrow (no greater than 200 kilohertz) bandwidths and many can operate close together within a six megahertz channel, so we expect their receivers to have good selectivity. Thus, the Commission believes that there is a low risk of unlicensed white space devices causing interference to licensed wireless microphones in the adjacent band.

76. The Commission seeks comment on this proposal for partitioning of the duplex gap between licensed wireless microphones and unlicensed white space devices and unlicensed wireless microphones. Our proposed split maximizes the frequency separation between a six megahertz segment of the duplex gap for unlicensed use and wireless downlink spectrum, thereby reducing the risk of interference to those adjacent band services as required by the Spectrum Act, but it does not provide any frequency separation between the six megahertz unlicensed segment and wireless uplink spectrum used for base stations. The one megahertz separation at the lower end of the duplex gap provides an additional margin of interference protection to wireless handsets from licensed wireless microphones. The Commission also seeks comment on other possible partitioning scenarios and whether other approaches would provide interference protection to adjacent wireless uplink and downlink services while maximizing use of the spectrum. For example, should the one megahertz buffer be located at the upper end of the duplex gap? Is it needed to provide increased interference protection to wireless uplink spectrum from unlicensed operations operating in a six megahertz bandwidth? If so, how would this scenario affect the operation of licensed microphones in the lower duplex gap? Could licensed wireless microphones operate in the lower four megahertz portion of the duplex gap without a one megahertz buffer to separate them from wireless downlink spectrum? Would that approach increase the interference risk to either licensed wireless microphones or wireless downlink spectrum? Do we need a buffer at both ends of the duplex gap to protect both wireless uplink and downlink services? If so, what size buffers are appropriate and how would increasing the number or size of those buffers affect the available spectrum for unlicensed white space and wireless microphone users? For example, if we were to require a one megahertz buffer at each end of the duplex gap, should we allow only three megahertz of spectrum for licensed wireless microphones at the lower end of the duplex gap and six megahertz for white space devices and unlicensed wireless microphones at the upper end? Parties should address how white space use in each scenario above would satisfy the Spectrum Act's requirement that no harmful interference is caused to licensed services.

b. Technical Rules for Fixed and Personal/Portable Operations

77. The Commission proposes to allow fixed and personal/portable white space devices to operate in the six megahertz segment of the duplex gap described above with a power level of 40 milliwatts. This is consistent with our proposal to allow 40 milliwatt white space device operation in the guard bands. The Commission does not believe that a buffer is necessary to protect wireless uplink services above the duplex gap since the receivers of interest are those in base stations, and it expects there to be a greater separation distance from base station receivers than from mobile receivers, thus reducing the likelihood of harmful interference. The Commission seeks comment on this proposal. Is the 40 milliwatt power level useful for unlicensed devices? Would the proposed power level and frequency separation adequately protect wireless uplink services in the upper adjacent band? Do we need to limit the HAAT of fixed devices to minimize the possibility of interference to licensed services outside the duplex gap and licensed wireless microphones within the duplex gap?

4. Channel 37

78. The WMTS is used for remote monitoring of patients' vital signs and other important health parameters (*e.g.,* pulse and respiration rates) inside medical facilities. WMTS includes devices that transport the data via a radio link to a remote location, such as a nurses' station, which is equipped with a specialized radio receiver. WMTS operates licensed stations on three bands, including 608–614 MHz (channel 37) in the UHF band. Health

care institutions are required to register their locations and coordinate the use of all three bands through the American Society for Health Care Engineering (ASHE) of the American Hospital Association—the designated frequency coordinator—prior to commencing operation. This process minimizes the potential of WMTS users from causing harmful interference to, and receiving harmful interference from, other WMTS devices.

79. RAS is a receive-only service that uses highly sensitive receivers to examine and study radio waves of cosmic origin. There are twelve RAS telescopes that have been using channel 37 or plan to use channel 37 in the near future. Of them, ten comprise the National Radio Astronomy Observatory's (NRAO's) Very Long Baseline Array (VLBA), which are distributed in several locations in the United States and its territories, and collect simultaneous observations that are combined to emulate a single telescope 5000 miles in diameter. The remaining two telescopes are single dish instruments. The Commission protects RAS from in-band harmful interference by imposing field strength limits on WMTS and requiring coordination of WMTS use within certain distances of RAS observatories.

80. In the *Incentive Auction R&O,* the Commission decided to permit unlicensed operations on channel 37, subject to the development of the appropriate technical parameters for such operations to protect the WMTS and RAS from harmful interference. It stated that authorizing the use of channel 37 for unlicensed operations would make additional spectrum available for unlicensed devices in areas of the country that are not in close proximity to hospitals or other medical facilities that use WMTS equipment, or to RAS sites.

81. The Commission recognizes the importance of WMTS to patient care, and will remain mindful of this critical function when developing these technical parameters. In this NPRM, the Commission proposes technical parameters below to protect the WMTS and RAS from harmful interference and will develop a full record on the issues raised in this proceeding before adopting final rules.

a. Power Limits and Separation Distances

82. *General technical requirements.* There are several different approaches that could be taken regarding the types of white space devices that we would permit to operate on channel 37. The most cautious approach would be to limit operations on channel 37 to fixed devices only and to require registration of the locations where the devices are used in the white spaces database. Fixed devices are required to register their location and operator information in the white spaces database because the rules permit them to operate at higher power than personal/portable devices. The registration requirement makes fixed devices easer to locate in the event harmful interference occurs. Another approach would be to allow both fixed and Mode II personal/portable devices to operate on channel 37. Like fixed devices, Mode II devices must incorporate geo-location and database access capabilities. Unlike fixed devices, they are not required to register with the database since their maximum permitted power is lower than that allowed for fixed devices, and their operating location changes frequently. A third approach would be to allow fixed and both Mode I and Mode II personal/portable devices to operate on channel 37. Mode I devices are not required to incorporate a geo-location capability and obtain their list of available channels from a fixed or Mode II device that is within their transmission range. Thus, the separation distances we calculate below to protect the WMTS and RAS may need to be increased if Mode I devices are permitted to operate on or adjacent to channel 37.

83. The Commission seeks comment on the types of white space devices that should be permitted to operate on channel 37. If we allow personal/portable devices to operate on channel 37, should we require them to register with the white spaces database, and if so, what registration information should be required? What interference concerns are raised by allowing personal/portable devices on channel 37, and how could these be addressed, particularly those involving Mode I devices? Are there technology solutions or other means to mitigate the risk? Would we need to specify greater separation distances for personal/portable devices than for fixed devices of comparable power levels? If we initially allow only fixed devices on channel 37, should we then allow personal/portable devices at a later date once we have confidence that they will not cause harmful interference to the WMTS and RAS? The Commission seeks comment on any studies that address the interference potential of personal/portable devices to the WMTS and RAS.

84. The Commission proposes to allow the same maximum four watt EIRP for channel 37 fixed white space devices that is allowed for fixed devices in the TV bands. If we allow personal/portable devices on channel 37, we propose that the maximum EIRP would be 100 milliwatts, consistent with the current rules for operation in the TV bands. However, as discussed, these power levels may need to be reduced depending on what devices operate in the adjacent bands. The Commission also proposes to require white space devices on channel 37 to meet the other technical requirements for white space devices, including the conducted power, antenna gain and PSD limits as appropriate. The Commission further proposes that these devices must access a database over the internet to determine if channel 37 is available at their location, meaning that the location is sufficiently far removed from all WMTS and RAS sites to avoid causing harmful interference. The required separation distances are discussed in the following paragraphs.

85. *Power limits.* The maximum power at which an unlicensed device can operate may be limited based upon the need to protect authorized services in adjacent bands, in addition to services in the same band. For example, neither the current rules nor our proposals discussed above permit fixed devices to operate at four watts in bands immediately adjacent to occupied TV channels. Currently, the adjacent spectrum bands to channel 37 (channels 36 and 38) are allocated for TV broadcasting. After the incentive auction, this situation may or may not change depending upon the amount of spectrum recovered in the auction. There are three possible scenarios. First, if less than 84 megahertz of spectrum is recovered, channels 36 and 38 will continue to be available for TV broadcasting, so there will be essentially no change from the current situation. Second, if exactly 84 megahertz of spectrum is recovered, channel 36 will continue to be available for TV broadcasting, while channel 38 will not. Instead, there will be a three megahertz guard band directly above channel 37 which will separate channel 37 from licensed wireless downlink spectrum. Third, if more than 84 megahertz of spectrum is recovered, there will be three megahertz guard bands above and below channel 37 to separate channel 37 from licensed wireless downlink spectrum.

86. Under the first scenario, channel 37 in a particular location could be treated similarly to any other television channel, provided it is sufficiently far removed from the WMTS and RAS to avoid harmful interference. The Commission therefore proposes to permit fixed white space devices to operate with an EIRP of up to four watts

on channel 37, provided channels 36 and 38 are also vacant. If we allow personal/portable device operation, we propose that the maximum EIRP would be limited to 100 milliwatts in this scenario. In locations where channel 37 is available, but both channels 36 and 38 are occupied, the Commission proposes to allow a maximum allowable power of 40 milliwatts to protect television services on the adjacent channels. In locations where channel 37 is available, but only one of the adjacent channels is occupied, the Commission proposes to allow fixed unlicensed device operation with a maximum power of 4 watts EIRP, where the device operates in the six megahertz band centered on the boundaries of channel 37 and the unoccupied channel.

87. Under the second scenario (84 megahertz recovered), the Commission proposes to allow a maximum white space device power of 40 milliwatts EIRP on channel 37 to protect wireless downlink services that will be three megahertz above channel 37 and to protect television on channel 36 if that channel is occupied. If channel 36 is vacant, a white space device could also operate at 40 milliwatts, and possibly higher, in a six megahertz band centered on the boundary of channels 36 and 37, leaving a three megahertz separation from channel 35 and a six megahertz separation from wireless downlink spectrum.

88. Under the third scenario (more than 84 megahertz recovered), we propose to allow a maximum white space device power of 40 milliwatts on channel 37 where there will be a three megahertz guard band on each side of channel 37 to protect licensed wireless downlink services in the adjacent bands.

89. The Commission seeks comment on these proposals. In particular, it seeks comment on the appropriateness of the proposed power limits for white space devices in each of these scenarios. Should these limits be lower to reduce the likelihood of harmful interference to the WMTS, RAS and wireless downlink services? Conversely, could the proposed limits be higher without a risk of harmful interference? For example, could a white space device operate at power levels higher than 40 milliwatts under the second scenario with a three megahertz separation to TV and a six megahertz separation to wireless downlink services? If so, what is the maximum power that could be used? Should we allow a fixed device power limit on channel 37 that is higher than four watts in rural areas under those scenarios where we propose a four watt limit?

90. *Determination of WMTS separation distances.* WMTS systems typically consist of small patient-worn transmitters and receive antennas located within a healthcare facility. According to GE, WMTS transmitters are frequency-division multiplexed with typical occupied bandwidth of 10 kHz and a relatively low transmit power of less than 0 dBm (1 milliwatt) to extend battery life. GE argues that, to prevent interference to the WMTS, the signal level at the perimeter of a registered WMTS facility should not exceed 10 microvolts per meter within a 100 kilohertz bandwidth on channel 37, or 20 millivolts per meter within a one megahertz bandwidth on channels 36 and 38.

91. The Commission calculated the minimum co-channel separation distances that would be required for white space devices to meet GE's recommended field strength limit for channel 37. It used the TM 91–1 propagation model and white space device power levels that range from 40 milliwatts to 4,000 milliwatts in four dB steps. The Commission assumed that the WMTS transmitter would be at 10 meter height above ground, which is the highest height specified in the ASHE/AHA database, and used the same range of HAAT currently specified in the rules for fixed white space devices.

92. The Commission calculated the minimum required adjacent channel separation distances in two different ways using the same basic methodology that we used to determine the co-channel separation distances (TM 91–1 model, WMTS height of 10 meters, same range of white space device power and HAAT). First, it calculated the distances considering receiver ''blocking'' using the field strength limits on channels 36 and 38 that GE recommended to avoid interference. We then considered the out-of-band emission power that would fall into channel 37 from white space devices operating on channels 36 and 38 and calculated the minimum required separation distances based on GE's recommended field strength limit on channel 37. Based on our analysis, the effect of receiver blocking is greater than the effect of out-of-band emissions, so we considered receiver blocking in determining the minimum required separation distances.

93. The calculated co-channel and adjacent channel separation distances based on our methodology are shown in the two tables in paragraph 112 of the NPRM. These are the distances that would be required between a white space device and an individual WMTS receiver, and not the total distance that would be required to protect WMTS use that relies on large distributed antenna systems throughout buildings and that may be spread out across a large facility but represented by only single point in the database. The separation distances are rounded to the nearest tenth of a kilometer. In cases where the calculated adjacent channel separation distance is less than one tenth of a kilometer, we listed a separation of one tenth of a kilometer to avoid specifying extremely small distances. If we allow personal/portable devices on channel 37, the separation distances would be those at an HAAT of less than three meters at a power level of either 40 milliwatts or 100 milliwatts, depending on which authorized services are in the adjacent frequency bands. The Commission seeks comment on the appropriateness of these separation distances for protecting the WMTS as well as our methodology used to calculate them.

94. The current ASHE/AHA database allows the registration of only a single geographic point, whereas a hospital or health care facility is often a large building or group of building on a campus. The Commission also notes that GE stated that its recommended protection criteria for the WMTS should apply at the perimeter of a facility. For these reasons, the Commission expects that it will need to increase the calculated distances listed above to compensate for the fact that a single point may not accurately represent WMTS usage that could be spread out over a large facility. If so, what is the appropriate adjustment and why? For example, should we simply add an additional distance to our calculated distances? Alternatively, as discussed in the database section, should the Commission allow a facility to specify multiple points that define a bounded area around a large facility that uses the WMTS as opposed to specifying a single point?

95. The Commission also seeks comment on any ways it can simplify the process of protecting the WMTS. For example, there are thousands of registered WMTS sites, many of which are clustered close together in urban areas. Could we define exclusion zones in urban areas where operation is prohibited on channel 37 rather than requiring the databases to consider each individual WMTS location? If so, how should we define the exclusion zones and enter this information into the white spaces databases?

96. The Commission further seeks comment on whether there are any other requirements necessary to protect the WMTS. For example, would a limit on the HAAT of fixed devices on channel 37 reduce the potential for interference

to the WMTS? Should the Commission prohibit the operation of Mode I personal/portable devices on channels 36 and 38 since they rely on another device's geo-location capability and could possibly operate slightly closer to adjacent channel WMTS locations than the device that obtained the list of available channels? Alternatively, should the Commission limit operation on channel 36 and 38 to fixed devices only?

97. *Determination of RAS separation distances.* The Commission proposes different protection criteria for the ten VLBA stations than for the two single dish radio astronomy observatories because of their differing potential to receive interference. VLBA observations are less susceptible to interference than single dish observations because interfering signals do not correlate across the multiple receivers that comprise the array. The Commission proposes to require that white space devices operating on channel 37 comply with separation requirements based on their operating power to protect the ten VLBA observatories, and that they may not operate within defined exclusion zones around the two single dish observatories that receive on channel 37.

98. The Commission proposes requirements for white space devices to protect the VLBA based on the existing requirements that protect those stations from WMTS stations operating on channel 37. Section 95.1115(a) of the rules allows a maximum WMTS field strength on channel 37 of 200 millivolts per meter measured at a distance of three meters (this equates to an EIRP of approximately 12 mW). Further, § 95.1119(b) specifies that WMTS operations within 32 kilometers of the ten VLBA sites must coordinate with those sites. Using these two requirements as a basis, we can determine the minimum distance that a white space device must be from a VLBA site to provide the same level of protection as a WMTS transmitter located just outside the 32 kilometer coordination zone. Using the WMTS criterion, we calculate the appropriate path loss exponent to be 2.53. Therefore, the Commission proposes to calculate the separation distances between fixed white space devices and VLBA sites using a propagation model with a path loss exponent of 2.53. This model considers only the power of the white space device and not its antenna height above ground or average terrain.

99. Based on the foregoing, our calculated minimum co-channel separation distances between white space devices operating on channel 37 and VLBA sites are as listed in the table in paragraph 118 of the NPRM.

100. The Commission notes that in developing this table, factors which would act to shorten the protection distance such as buildings, mountains, trees or other ground clutter were not considered. In addition, because VLBA stations require very low noise environments, most have been constructed in remote areas that have substantial natural shielding due to the fore mentioned obstructions. Also, we note that most of these distances would be beyond the radio horizon for most, if not all, paths between white space devices and VLBA sites.

101. The Commission seeks comment on these separation distances and the methodology and assumptions used to calculate them. In particular, it seeks comment on whether these separation distances are appropriate for protecting the VLBA. Do they provide adequate protection to the VLBA? Are they greater than necessary to protect the VLBA? Should we place a cap on the maximum separation distances, such as 100 kilometers, to account for the fact our analysis did not account for any factors as mentioned above that would act to shorten the required separation distances and that radio astronomy sites will be beyond the radio horizon in most instances? Are the assumptions made in our analysis reasonable? For example, would a different propagation model or different protection criteria for the VLBA be more appropriate? Is so, what model or criteria should we use to determine the minimum separation distances? Commenters on this issue should provide detailed technical criteria and analysis to justify their position.

102. The Commission also seeks comment on whether it should establish adjacent channel separation distances between white space devices operating on channels 36 and 38 and the ten VLBA observatories. Under the current rules, white space devices cannot operate on these channels because they are reserved for wireless microphones if they are not being used by television stations. However the Commission will allow white space devices to operate on these channels if they are still available for television broadcasting after the incentive auction and are not being used by a television station at a white space device's location. Under the current rules, white space devices must operate at least 2.4 kilometers away from VLBA sites, so this requirement would apply to white space devices operating on channels 36 and 38. Is this adjacent channel separation distance adequate to protect the VLBA observatories? If not, what is the appropriate separation distance and why?

103. With respect to the two single dish RAS observatories that receive on channel 37 (Green Bank Telescope and Arecibo Observatory), § 1.924 of the rules defines coordination requirements to protect them. Specifically, § 1.924(a) requires parties planning to construct and operate a new or modified station at a permanent fixed location within a specified quiet zone around the National Radio Astronomy Observatory at Green Bank West Virginia to notify the observatory in writing of the technical details of the proposed operation. Similarly, § 1.924(d) requires parties planning to construct and operate a new station at a permanent fixed location on the islands of Puerto Rico, Desecheo, Mona, Vieques or Culebra to notify the Interference Office of the Arecibo Observatory in writing or electronically of the technical parameters of the planned operation.

104. Because the Commission does not believe it reasonable for operators of white space devices to coordinate with the Green Bank and Arecibo Observatories, and because separation distances to protect these observatories would be extremely large, the Commission is proposing that white space devices not operate on channel 37 within the National Radio Quiet Zone around Green Bank or on the islands of Puerto Rico, Desecheo, Mona, Vieques or Culebra. Much of the quiet zones are in less populated areas, and the Commission expects that in these areas there will be many other channels available for white space operation in addition to spectrum in the guard bands and duplex gap. However, the Commission seeks comment on whether there are ways to allow operation of white space devices on channel 37 within these areas. For example, are there coordination procedures that white space device operators and/or white space database administrators could follow to enable operation in these areas?

105. The Commission also seeks comment on whether it could establish minimum separation distances that white space devices must meet to protect the Green Bank Telescope and the Arecibo Observatory that would affect a smaller area than the existing quiet zones. If so, what are the appropriate interference assumptions, propagation model and separation distances? Because we are proposing protection criteria for white space devices over a range of power levels and HAAT, could we establish smaller exclusion zones for white space devices that operate at lower power levels or

lower HAAT? If so, how should we determine these zones or separation distances?

b. Guard Bands Adjacent to Channel 37

106. Under certain spectrum recovery scenarios, there will be a three megahertz guard band on one or both sides of channel 37, resulting in a contiguous block of nine or 12 megahertz of spectrum. The Commission seeks comment on whether these guard bands could be combined with the six megahertz of channel 37 spectrum in areas where it is not being used for the RAS and WMTS to create a wider band for white space device use. If so, what power level, frequency separation and other technical requirements would be necessary to protect wireless downlink services adjacent to these guard bands?

c. Out-of-Band Emission Limits on Channels 36–38

107. The Commission requires white space devices to comply with out-of-band emission limits on channels 36 through 38 in addition to the adjacent channel and § 15.209 limits that white space devices must meet on other channels. The white space device out-of-band emission limit on channel 37 is significantly more stringent (approximately 25 dB lower) than the Section 15.209 limit on this channel. Manufacturers must incorporate an additional band-reject filter into white space devices to comply with the limit on channel 37. The high level of attenuation needed to meet the limit requires a sharp roll-off across channels 36 and 38, which may extend as far as channels 35 and 37, potentially precluding the use of all four of those channels by white space devices. The emission limits on channels 36 through 38 were originally recommended by GE Healthcare to protect the WMTS from interference by personal/portable white space devices that could be used in close proximity to WMTS receive antennas. The Commission adopted these recommended limits and applied them to fixed devices as well as personal/portable devices.

108. The inability of white space devices to use channels 36 and 38 was not previously a concern since the rules did not permit their use by white space devices. However, in the *Incentive Auction R&O,* the Commission decided to stop reserving two vacant channels exclusively for wireless microphones and to make them available for both white space devices and wireless microphones, provided those channels are not repurposed for licensed wireless broadband use. At the same time, we can also take steps to ensure that channels 35 and 39 can be used by white space devices, provided those channels are available after the incentive auction. Additionally, because the Commission is allowing unlicensed devices to operate on channel 37, it needs to remove the stringent emission limit that applies on that channel.

109. The Commission is proposing to remove the out-of-band emission limits that apply on channels 36 through 38 and instead require white space devices to meet either the current adjacent channel or the § 15.209 emission limits as appropriate. Our proposal to allow white space device operation on channel 37 requires that the devices access a database to ensure that they will operate sufficiently far from both WMTS and RAS sites to avoid causing interference to these services. The database will enforce both co-channel and adjacent channel separation distances from the WMTS, which will ensure that emissions that fall within channel 37 do not cause harmful interference to the WMTS. Thus, there will no longer be a need for the more stringent out-of-band emission limits on channels 36 through 38. This proposed change will eliminate the need for white space devices to incorporate additional filtering that blocks channel 37 and impacts the first and second adjacent channels, thus making channels 35, 36, 37, 38 and 39 useable by white space devices. The Commission seeks comment on this proposal.

5. Repurposed 600 MHz Band

110. The Commission is proposing technical criteria for protecting licensed wireless services that will operate in the 600 MHz Band from interference from white space device operations. These criteria will be applicable in two situations. First, the Commission decided to permit the continued operation of white space devices in repurposed spectrum except in those areas in which a 600 MHz Band licensee commences operations. It took this action because it expects that 600 MHz Band licensees will be commencing operations at different places at different times, depending on their business plans and other factors, both during and after the post-auction transition period. Some of the repurposed television spectrum may not be used for licensed wireless services in some areas for a considerable amount of time.

111. Second, the Commission decided to allow market variation in developing the 600 MHz Band Plan. Therefore, some spectrum may be assigned for broadcasting in some areas and licensed wireless services in others. The Commission decided in the *Incentive Auction R&O* to allow the continued use of white space devices on all spectrum that remains allocated for TV broadcasting, which would include that spectrum with uses that vary by market. Since both white space devices and licensed wireless services can potentially operate on the same frequencies due to market variation, we need technical requirements to prevent harmful interference between the services.

112. The current white space device rules contain protection requirements for a variety of services that operate in the TV bands, but they do not contain protection requirements for licensed wireless broadband services as such wireless services did not operate in the TV bands at the time the Commission adopted those rules. Therefore, the Commission proposes to develop appropriate protection criteria, specifically, minimum distance separations, to protect these wireless services. These criteria will be used by the white space databases to ensure that unlicensed operations no longer occur on a channel in an area in which a licensee has commenced operations. When a 600 MHz Band licensee plans to commence operations on frequencies that includes spectrum available for unlicensed operations under the rules for white space devices, that licensee can notify any of the white spaces database administrators when and where it plans to commence operations. The white spaces databases would then preclude unlicensed operations in those areas on the channels in use for wireless systems. We discuss the proposed methodology that will be used to place 600 MHz Band licensee information in the databases below.

113. Consistent with our discussion above with respect to the guard bands and duplex gap, the Commission seeks comment on whether it should allow both Mode I and Mode II personal/portable devices, in addition to fixed devices, to operate in the repurposed 600 MHz band. The Commission asks commenters to address the effect that any limitation on the permissible types of devices in this band may have on the development of white space services and applications. For commenters that believe Mode I personal/portable white space devices should be permitted in these bands, the Commission seeks comment on the typical operating range of such a device, as that range will need to be incorporated into many of the protection distances proposed in the sections that follow. With respect to Mode II personal/portable devices, the current white space rules assume

protection distances for these devices based on them not operating above three meters HAAT. Thus, for all protection criteria that follows below, we propose that protection from Mode II personal/portable devices be based on operating at that low HAAT. The Commission seeks comment on this proposal.

114. Depending on the channel used by a white space device, it could be in the same band as either wireless uplinks or downlinks. Therefore, the Commission proposes co- and adjacent channel protection criteria for both wireless uplinks and downlinks.

115. *Wireless uplinks.* Wireless uplinks are the transmissions from mobile devices to fixed base stations. The receivers of concern in developing protection criteria are therefore those in fixed base stations. The Commission proposes that 600 MHz licensees provide information to the white space databases which defines a polygon representing the outer edge of their base station deployment. Using that information, the Commission proposes to protect fixed stations by determining the minimum separation distance needed between a white space device and that polygon to prevent harmful interference. Because the amount of spectrum available for white space devices in this band will shrink over time as 600 MHz Band licensees build-out their systems, there is little benefit in developing complex criteria to manage white space device use in this band. Thus, this Commission is taking a simple approach in developing protection criteria based on the worst case of a white space device emission fully overlapping the receive band of a base station. However, the Commission proposes that the co-channel protection requirements apply for any amount of frequency overlap between a channel used by a white space device and a five megahertz spectrum block used by a part 27 licensee.

116. To determine the necessary separation distance to protect 600 MHz Band base stations, we must make certain assumptions regarding their usage. As already stated the Commission is assuming the worst case for this preliminary analysis and basing the protection distance on 5/6 of the total energy of the white space device being present in the base station receiver pass band. In addition, it assumes, consistent with other analysis throughout the incentive auction proceeding as well as in this instant proceeding, that a typical base station operates at 30 meters or less above ground level and that a white space device can operate at various heights up to 250 meters above average terrain. Further, the Commissions bases its analysis on the base station receiver sensitivity level of the 3GPP standard of −101.5 dBm for wide area base stations. The Commission believes this is the correct criteria for this analysis rather than assuming actual operation at 10 dB or more above this level as in other analyses in this proceeding. In those analyses, adjacent channel operations were being protected mostly in areas of high wireless signal levels. However, here, we are specifically protecting base stations at the outer edge of a 600 MHz Band licensees coverage area that are providing service to the most distant subscribers. Using the TM 91–1 propagation model, the Commission believes the separation distances (rounded to the nearest kilometer) from the polygon representing the edge of base station deployment will protect base station operations from harmful interference from co-channel white space devices, see table in paragraph 135 of the NPRM.

117. The Commission therefore proposes that white space devices adhere to these separation distances from the edge of the polygon defining the location of base stations as provided by the 600 MHz Band licensees, and that these criteria will be enforced by the white space databases to protect co-channel 600 MHz base stations in the repurposed TV spectrum. In making this proposal, which provides for a maximum separation distance of 60 kilometers, we recognize that based strictly on calculations, the distances could be much greater. However, the line-of-sight radio horizon for a 30 meter high base station antenna and a 250 meter high white space device antenna is 87 kilometers. Thus, there is no reason for distances to be greater than that. Further, that line-of-sight radio horizon assumes perfect atmospheric conditions, and the absence of any obstructions such as buildings, mountains, trees or other ground clutter which further acts to reduce actual operating range. In addition, although the Commission developed these distances based on full overlap of the white space device's emissions with the base station receiver, there may be many cases where the overlap is less and thus, these proposed distances will provide additional protection. The Commission therefore, believes that the 60 kilometer maximum separation distance is reasonable and seeks comment on this proposal. The Commission asks that commenters address our assumptions and conclusions and provide technical information and analysis if they believe we should use different criteria or whether we should take a different approach to protecting these stations.

118. In the repurposed 600 MHz Band, white space devices may also be operating on an adjacent channel to wireless licensees. In these situations, the white space device must comply with certain separation distances to provide the required protection to avoid causing harmful interference. In this instance, we are defining adjacent channel operations as any overlap of a white space device's six megahertz operating channel with any portion of a five megahertz block directly adjacent to a five megahertz block that is being used by a 600 MHz base station. As with our proposal for co-channel separation, we recognize that in many cases, white space devices will operate with a greater frequency separation from 600 MHz base stations than we use in our analysis, but for the same reasons stated in the proposal to protect co-channel operations, we base our proposed separation distances on the worst case situation where a white space device operates immediately adjacent to a five megahertz block used by a 600 MHz base station (*i.e.,* with a zero megahertz frequency offset).

119. In conducting our analysis to determine the necessary protection distances, the Commission assumes, similar to our analysis for handset protection, that the base station is operating 10 dB above its sensitivity level of −101.5 dBm. The Commission also assumes an adjacent channel selectivity of 43.5 dB. In addition, we assume a wireless base station filter roll-off of 5.7 dB/MHz. Based on these assumptions, we calculated the separation distance values for white space devices to protect 600 MHz wireless base stations, see table in paragraph 138 of the NPRM.

120. The Commission therefore proposes that white space devices operating in the repurposed 600 MHz Band maintain these adjacent channel separation distances from the edges of the boundary defined by the 600 MHz Band licensees defining the area in which their base stations are located. This requirement will be enforced through the white space databases. The Commission seeks comment on this proposal and our assumptions. Commenters who believe that different separation criteria are needed should provide detailed comments and analysis containing all assumptions and analysis.

121. *Wireless downlinks.* Wireless downlinks are the transmissions from fixed base stations to mobile devices. The receivers of concern in developing protection criteria in the wireless downlink spectrum are therefore the

mobile device's receivers. A database cannot track the constantly changing locations of mobile devices, so the protection criteria must be based on base station location. The Commission proposes to calculate the required separation distances as follows. First, it proposes to define the minimum separation distance necessary to protect a mobile device from interference from a white space device. Then it proposes to define a maximum distance from base stations at which mobile devices would typically operate. The minimum required separation distance from the boundary of the area in which base stations operate would be the sum of these two distances.

122. As with our approach for base stations, our goal is to provide a simple mechanism for protecting 600 MHz Band handsets from co-channel interference from white space devices. For our preliminary analysis, we use the same assumptions as for the analysis for base stations above except that we use the handset sensitivity of −97 dBm and assume that handsets operate 1.5 meters above the ground. Based on those assumptions, the Commission calculated the separation distances to protect 600 MHz Band handsets from white space devices, see table in paragraph 141 of the NPRM.

123. Inspecting this table reveals that the protection distance for white space devices operating at maximum height are not that much greater than for those operating near ground level. Therefore, for simplicity, we will base our proposal only on the single separation distance corresponding to the largest calculated—4.2 km. To calculate the total separation distance from a base station to protect handsets, we must also provide a maximum distance from a 600 MHz band base station at which mobile devices would typically operate. We believe that assuming a maximum of 30 km for this distance is reasonable. The Commission therefore proposes that personal/portable white space devices maintain a minimum distance of 35 kilometers from the edge of the carrier's defined base station deployment. This distance will be enforced through the white space databases. The Commission seeks comment on this proposal and our assumptions and asks that commenters who disagree provide detailed technical analysis supporting their conclusions.

124. As with protection of adjacent channel 600 MHz base stations, we also need criteria to protect adjacent channel handsets. Using the same assumptions for handsets as used above for interference analysis between wireless handsets in the duplex gap and white space devices and assuming the worst case of no frequency separation between the edge of the handset receive band and the white space transmit band, we calculated the separation distances to protect handsets from interference, see table in paragraph 143 of the NPRM.

125. Under the same reasoning as used above; that is assuming a maximum 30 kilometer service areas for wireless handsets around a base station, and using the largest protection distance calculated, the Commission proposes that white space devices operating adjacent channel to 600 MHz systems maintain a 31 kilometer distance from the edge of the area defined by the wireless licensees that contains their base stations. The Commission seeks comment on this proposal and our assumptions and ask that commenters who disagree provide detailed technical analysis supporting their conclusions.

B. Wireless Microphones

126. In 2010, the Commission issued a waiver to permit unlicensed wireless microphones in the television bands under part 15 pursuant to certain technical rules. The Commission stated that this waiver would remain in place until such time as final rules for their operations were established. The Commission also sought comment on proposed part 15 rules for unlicensed wireless microphone operations in the TV bands. In particular, the Commission proposed to define these devices as intentional radiators used to transmit voice, music, or other audio material over short distances. It also proposed to permit these devices to operate with a power level to the antenna of up to 50 milliwatts in both the VHF and UHF TV bands, and proposed technical rules that were in many respects similar to the technical rules applicable to devices licensed under part 74 as low power auxiliary stations.

127. The Commission continues to believe that it should codify part 15 rules for the operation of unlicensed wireless microphones in the TV bands, but we believe that the Commission's 2010 proposals should be modified for a number of reasons. Subsequent to these proposals, the Commission adopted rules for the incentive auction, which will reduce the number of TV channels where wireless microphones can operate. The *Incentive Auction R&O,* also changed the method for determining the minimum separation between licensed part 74 wireless microphones and co-channel TV stations, and the Commission believes it should consider the same approach for unlicensed wireless microphones. In addition, because there will be less TV spectrum available for wireless microphones after the incentive auction, the Commission believes it should consider modifying the out-of-band emission limits for wireless microphones to enable more efficient spectrum use. Finally, upon further consideration, we believe that the Commission's previous proposed definition for unlicensed wireless microphones is overly broad and should be modified. Thus, the proposals in this NPRM supersede those made by the Commission in the 2010. The Commission will therefore not carry over the record from the previous proceeding concerning the proposals to codify part 15 rules for unlicensed wireless microphones. Parties that wish to comment on this issue must file comments in this proceeding.

1. Unlicensed Wireless Microphones in the TV Bands

128. *Definition of unlicensed wireless microphones in part 15.* The Commission proposes to define a wireless microphone as a device that converts sound into electrical audio signals that are transmitted using radio signals to a receiver which converts the radio signals back into audio signals that are sent through a sound recording or amplifying system. The Commission also proposes that wireless microphones may be used for cue and control communications and synchronization of TV camera signals as defined in § 74.801. The Commission further proposes that this definition would not include auditory assistance devices as defined in§ 15.3(a). The commission believes that this definition would encompass the types of wireless microphones that currently operate within the TV bands, but is not so broad as to encompass other types of unlicensed devices that already have provisions in part 15 for operation outside the TV bands. The Commission seeks comment on this definition.

129. *Permissible frequencies of operation.* The Commission proposes to allow unlicensed wireless microphones to operate in the TV spectrum on channels 2–51, excluding channel 37 in all locations and channel 17 in Hawaii, which is allocated for non-broadcast purposes. Since the number of TV channels that will be available for unlicensed wireless microphones will be reduced after the incentive auction, the Commission also proposes to add an advisory in the rules indicating that the highest channel available for wireless microphones will be determined by the outcome of the incentive auction and will be modified consistent with the auction results. The Commission seeks comment on these proposals. The

Commission also seeks comment on whether it should allow unlicensed wireless microphone operation on channels 14–20 in locations where the PLMRS/CMRS operates and whether there is a need to establish protection criteria for these services.

130. To prevent harmful interference to co-channel TV stations, the Commission proposes to require unlicensed wireless microphones to operate at least four kilometers outside the following protected service contours of co-channel TV stations, which is the same protection requirement that the Commission adopted in the *Incentive Auction R&O* for part 74 wireless microphones, see table in paragraph 150 of the NPRM.

131. *Technical requirements for unlicensed wireless microphones.* Consistent with the current technical rules that apply under the existing part 15 waiver and the Commission's previous proposals, we propose to permit wireless microphones to operate with a power level to the antenna of up to 50 milliwatts in both the VHF and UHF TV bands. The Commission expects that this proposed power level is appropriate for most users, particularly because we expect that parties using part 15 wireless microphones will typically be entities operating in smaller venues that do not require the longer range operation that higher power allows. The Commission seeks comment on the appropriateness of this power level. The Commission also seeks comment on whether the equipment certification rules should prohibit component parts such as amplifiers from being attached after-market to a microphone and whether the rules should specify a maximum field strength or other emission limits (*e.g.,* EIRP) for equipment instead of a conducted power level.

132. The Commission proposes to require unlicensed wireless microphones to comply with the same channelization, frequency stability, and bandwidth requirements as part 74 wireless microphones. Specifically, it proposes to require that operation be offset from the upper or lower channel edge by 25 kHz or an integral multiple thereof and that the operating frequency tolerance be 0.005 percent. The Commission also proposes to specify that one or more adjacent 25 kHz segments within a TV channel may be combined to form an operating channel with a maximum bandwidth not to exceed 200 kHz. Consistent with the measurement requirements for other part 15 transmitters, the Commission further proposes to require that the frequency tolerance be maintained over a temperature variation of −20 degrees to +50 degrees C at normal supply voltage, for a variation in the supply voltage from 85 percent to 115 percent of the rated supply voltage at a temperature of 20 degrees C, and that battery operated equipment be tested using a new battery. The Commission expects that the proposed 25 kHz offset requirement would prevent wireless microphones from operating at the edge of a TV channel where they could interfere with TV stations on adjacent channels, and the proposed frequency tolerance requirement would ensure that devices do not drift from the designated frequencies. The limit on the bandwidth that a wireless microphone may occupy will leave room for multiple microphones within a channel. The Commission seeks comment on these proposals.

133. The Commission proposes that unlicensed wireless microphones comply with the same emission mask that it is proposing for licensed part 74 wireless microphones in the Wireless Microphones proceeding. Specifically, The Commission proposes to require that emissions from analog and digital unlicensed wireless microphones comply with the emission masks in ETSI EN 300 422–1, *Electromagnetic compatibility and Radio spectrum Matters (ERM); Wireless microphones in the 25 MHz to 3 GHz frequency range; Part 1: Technical characteristics and methods of measurement.* Requiring wireless microphones to meet these tighter emission requirements will protect authorized services in adjacent bands from harmful interference, and will improve spectrum sharing by wireless microphones. In light of the fact that there will be fewer vacant TV channels available for wireless microphones and more intensive use of the remaining TV spectrum after the incentive auction, the Commission now proposes tighter emission limits for wireless microphones than it had previously proposed in 2010. Shure supports Commission adoption of these masks, stating that the reduced out-of-band emissions would facilitate tighter spacing of wireless microphones operating together within a TV channel.

134. The Commission also proposes to require that unlicensed wireless microphones comply with the § 15.209 emission limits outside the frequency range where the ETSI masks are defined (one megahertz above and below the wireless microphone carrier frequency). The Commission further proposes that emissions would not have to be attenuated below the limits in § 15.209, even if the ETSI mask would require greater attenuation.

135. The Commission seeks comment on these proposals. In particular, it seeks comment on the benefits of requiring unlicensed wireless microphones to comply with the ETSI limits, and whether these benefits would outweigh the costs. Are these limits necessary to protect authorized services in adjacent frequency bands? To what extent would compliance with the proposed limits improve spectrum sharing by wireless microphones? Would equipment manufacturers have difficulty in complying with these limits? Do any existing wireless microphones already comply with them? Are the § 15.209 emission limits appropriate beyond the range where the ETSI masks are defined, or should the limit at the outer edges of the ETSI masks (−90 dBc) apply at frequencies more than one megahertz removed from the wireless microphone carrier frequency? The Commission also seeks comment on whether it should specify separate emission masks for analog and digital microphones, or whether a single mask is sufficient. For example, ETSI EN 300 422–1 suggests that its mask for digital microphones could also be used for analog microphones. Should the Commission incorporate the ETSI standard by reference into the rules, or should it simply specify the emission mask(s) in the part 15 rules?

136. Reducing the required separation distance between wireless microphones and co-channel television stations could increase the number of locations where wireless microphones could operate. The Commission seeks comment on whether it could reduce the proposed four kilometer separation distance, which was calculated using a power level of 4,000 milliwatts. Is this a realistic assumption for the combined power level of multiple wireless microphones operating within a television channel? Should we assume a lower power level? If so, what is the appropriate power level and separation distance? How much would a shorter separation distance benefit wireless microphone users?

137. Finally, the Commission seeks comment on whether any other technical requirements need to be specified for unlicensed wireless microphones. For example, the part 74 rules for low power auxiliary stations have additional requirements for wireless microphones including a maximum frequency deviation specification when frequency modulation is used. Additionally, part 74 states that a transmitter may be either frequency synthesized or crystal controlled. The Commission seeks comment on whether these or any other

requirements should be incorporated into the part 15 rules for wireless microphones.

2. 600 MHz Guard Bands and Duplex Gap

a. Unlicensed Wireless Microphones

138. Unlicensed wireless microphones will be permitted to operate in the 600 MHz Band Plan guard bands, including the duplex gap. The Commission proposes to require that unlicensed wireless microphones that operate in the guard bands and duplex gap meet many of the same technical requirements that it proposes in this NPRM for unlicensed wireless microphones that operate in the TV bands. Specifically, the Commission proposes the same definition of wireless microphone, since it believes that we should have a uniform definition for unlicensed wireless microphones regardless of the bands in which they operate. The Commission also proposes to require that unlicensed wireless microphones that operate in the guard bands and duplex gap comply with the same channelization, bandwidth, frequency stability and emission mask requirements as wireless microphones that operate in the TV bands. These requirements are necessary in the guard bands and duplex gap as well as the TV bands to enable more efficient use of spectrum and prevent harmful interference to authorized services outside the bands where wireless microphones operate. The Commission seeks comment on these proposals.

139. *Frequencies of operation.* The Commission proposes to allow unlicensed wireless microphones to operate in certain segments of the guard bands and duplex gap. Specifically, it proposes to allow unlicensed wireless microphones to operate in the same six megahertz portion of the duplex gap as white space devices. In the guard band between television and wireless downlink spectrum, the Commission proposes that unlicensed wireless microphones may operate across the guard band with the exception of a one megahertz segment at the upper end that would act as a buffer between unlicensed wireless microphone operations and wireless downlink services. As with white space devices, the amount of spectrum available for wireless microphone operation in the guard band would depend on the size of the guard band and amount of frequency separation needed to protect wireless services from harmful interference. For example, if the guard band is 11 megahertz wide, unlicensed wireless microphones would be allowed to operate in the lower ten megahertz segment of the band; if the guard band is nine megahertz wide, unlicensed wireless microphones would be allowed to operate in the lower eight megahertz segment; and if the guard band is seven megahertz wide, unlicensed wireless microphones would be allowed to operate in the lower six megahertz segment. The Commission seeks comment on the amount of frequency separation needed between wireless microphones and wireless services in the adjacent bands in the duplex gap and guard bands. In the three megahertz guard bands adjacent to channel 37, the Commission proposes to allow unlicensed wireless microphones to operate in the two megahertz segment closest to channel 37, leaving a one megahertz buffer to protect wireless downlink services adjacent to these guard bands. The Commission seeks comment on these proposals.

140. *Power limits.* The Commission proposes that unlicensed wireless microphones operating in the guard bands and duplex gap operate with a maximum conducted power output of 20 milliwatts to the antenna. This is less than the 50 milliwatt power level it proposed for unlicensed wireless microphones in the TV bands, but would still be useful by wireless microphone operators, since many wireless microphones operate at power levels between 10 and 20 milliwatts. The Commission believes that this lower power limit for wireless microphones is necessary in the guard bands and duplex gap to protect licensed wireless services outside these frequency bands. In addition, since the Commission is proposing that white space devices can operate in the guard bands and duplex gap at power levels of 40 milliwatts, limiting the power of unlicensed wireless microphones can help enable coexistence between unlicensed wireless microphones and white space devices by making both types of devices operate at more comparable power levels. Wireless microphones operate in 200 kilohertz channels as opposed to the six megahertz (6000 kilohertz) channels used by white space devices, and as many as 16 wireless microphones potentially could operate in the same amount of spectrum as a single white space device. Thus, the aggregate wireless microphone power within a six megahertz channel can be greater than a white space device power within a six megahertz channel. The Commission recognizes that even at our proposed lower power level for unlicensed wireless microphones in the guard bands and duplex gap, there would still be a disparity between the aggregate power for wireless microphones and the power for white space devices, but the lower power level we propose for wireless microphones in these bands would reduce this disparity.

141. The Commission seeks comment on the proposed power level for unlicensed wireless microphones. Is this power level useful for unlicensed wireless microphones? Will it provide adequate protection for wireless uplink and downlink services as well as TV broadcasting services? How would the power limit for unlicensed wireless microphones impact the ability of a white space device to operate co-frequency in the duplex gap, *i.e.,* would the operation of one device preclude the operation of the other? Should the proposed power level be reduced further to allow for better coexistence between unlicensed wireless microphones and white space devices? Alternatively, could the proposed power level be increased without causing interference to authorized services or adversely affecting white space operations?

142. *Database access.* The Spectrum Act states that the Commission may permit unlicensed use of the guard bands, and stipulates that (a) unlicensed use shall rely on a database or subsequent methodology as determined by the Commission, and (b) the Commission may not permit any use of a guard band that the Commission determines would cause harmful interference to licensed services. The Commission's part 15 rules already require that unlicensed devices not cause harmful interference to and must accept interference from authorized users. In this NPRM, the Commission proposes and seek comment on technical and operational rules for unlicensed wireless microphones in the guard bands and duplex gap that would satisfy the requirements of both the Spectrum Act and our rules that unlicensed wireless microphones not cause harmful interference to authorized services.

143. Unlike fixed and personal/portable white space devices that are required to comply with rules that clearly satisfy the Spectrum Act's stipulation that ''unlicensed use shall rely on a database,'' wireless microphones do not operate in a similar way to ''rely on a database.'' Nonetheless, the Commission proposes that unlicensed wireless microphones that operate in the guard bands and duplex gap must ''rely on a database'' prior to operation to ensure that their intended operating frequencies are

available for unlicensed wireless microphones at the location where they will be used. The Commission believes this proposed requirement is necessary because during the post-auction transition period, there will be a time when TV stations continue to operate in spectrum that will eventually become the guard bands and duplex gap, so the database will indicate to users whether operation is permitted in the guard bands and duplex gap. Also, there may be market variation in the amount of spectrum recovered, so the frequency and size of the guard band between TV and wireless downlink spectrum may differ in different parts of the country. Thus, the database can indicate which spectrum is available for unlicensed wireless microphones at a particular location. The Commission believes that this requirement is not unduly burdensome because there are several white space databases available, and unlicensed wireless microphone users will have an incentive to check a database to identify available frequencies for their use. The Commission seeks comment on this proposal.

144. The Commission seeks comment on how unlicensed wireless microphones would comply with the Spectrum Act's stipulation that the devices rely on a database or subsequent methodology. For example, could wireless microphones be designed to access directly a database through an Internet connection and download a list of available frequencies of operation in the same manner as white space devices? Would such an approach be practical, and would it add cost and complexity to wireless microphones? Would requiring users of unlicensed wireless microphones to manually check a database through another device, *e.g.,* a laptop or smart phone, to get a list of available frequencies of operation comply with the Act's stipulation ''to rely on a database'' and ensure that the devices operate only in permissible frequency bands? Alternatively, would manual database checking be a ''subsequent methodology'' which is permitted by the Spectrum Act in lieu of a database? Are there alternative methodologies that could be used in compliance with the Act? The Commission notes that after the end of the post-auction transition period, the duplex gap would be cleared of all broadcasters and would be uniform nationwide. Would designating a nationwide six megahertz block of spectrum in the duplex gap exclusively for unlicensed operation constitute a ''subsequent methodology'' under the Spectrum Act, and therefore eliminate the need for a database access requirement for both white space devices and wireless microphones?

b. Licensed Wireless Microphones in the Duplex Gap

145. The Commission proposes to require that licensed wireless microphones operating in the duplex gap comply with the same technical requirements described for unlicensed wireless microphones in the guard bands and duplex gap, with the following two exceptions. First, the Commission proposes that the permissible frequencies of operation would be limited to the four megahertz segment of the duplex gap which it proposes to designate for licensed wireless microphone use. Second, the Commission is not proposing to require licensed users to access a database before beginning operation because it does not believe such a requirement is necessary. At the end of the post-auction transition period, the duplex gap will be cleared of all broadcast operations, including low power TV and translator stations, and the duplex gap will be uniform nationwide. Thus, there will be no need for database access to determine whether the four megahertz segment of the duplex gap is available. During the post-auction transition period, however, a licensed wireless microphone user may need to determine whether the duplex gap is available in an area. The Commission believes that broadcaster and cable programming network entities that will be licensed to operate in the duplex gap are sophisticated users that are capable of determining whether the duplex gap is available at their location. Thus, the Commission does not believe it necessary to propose rules requiring licensed users of the four megahertz segment of the duplex gap to access a database to determine frequency availability. Since we are proposing to limit operation in this four megahertz segment to licensed users, there is no statutory requirement that use must rely on database access or a subsequent methodology determined by the Commission. The Commission seeks comment on these proposals. The Commission also seeks comment, regarding the splitting of the duplex gap, whether licensed wireless microphones could protect wireless services in the adjacent band from harmful interference.

3. Repurposed 600 MHz Band

146. In the *Incentive Auction R&O,* the Commission decided to permit wireless microphone users to continue to operate in the 600 MHz Band during the Post-Auction Transition Period subject to certain conditions. Specifically, wireless microphone users must cease operations in the 600 MHz Band if they cause harmful interference to any 600 MHz licensee's operations, and they must accept interference received from these operations. The Commission also decided that all wireless microphone operations must be transitioned out of the 600 MHz Band no later than the end of the Post-Auction Transition Period, which will be 39 months after the issuance of the *Channel Reassignment PN.* The Commission did not adopt any specific criteria to prevent harmful interference from wireless microphones to 600 MHz Band licensees, such as minimum separation distances from a co-channel wireless licensee's service area.

147. The Commission proposes that both licensed and unlicensed wireless microphones operating in the repurposed 600 MHz Band during the Post-Auction Transition Period comply with minimum separation distance requirements to prevent harmful interference to 600 MHz Band licensees. The Commission believes that protection requirements are necessary because wireless microphones could cause harmful interference to 600 MHz Band equipment (*e.g.,* handsets) while not receiving any interference since 600 MHz Band equipment transmits and receives on different frequencies. Thus, the wireless microphone operator may be unaware that it is causing harmful interference, and the party receiving the harmful interference may be unaware of its source.

148. The Commission proposes to protect 600 MHz Band licensees from harmful interference from wireless microphones using the same criteria we propose to protect 600 MHz Band licensees from harmful interference from white space devices. Specifically, the Commission proposes to require that wireless microphones operate at the same distance outside a 600 MHz Band licensee's service area as white space devices operating with a power of 4,000 milliwatts EIRP and an antenna height of three meters above average terrain. This is similar to the approach the Commission used in the *Incentive Auction R&O* to determine the minimum separation distance between wireless microphones and the protected contour of co-channel television stations. In that case, the Commission based its determination on a power level significantly higher than a single wireless microphone since multiple wireless microphones can operate in a single six megahertz channel. It used the

three meter antenna height above average terrain because that height is used in determining the separation distances for portable white space devices, and wireless microphones are also portable devices. Are the proposed protection distances appropriate, or do we need to increase or decrease them? The Commission seeks comment on this proposal.

149. The Commission also seeks comment on how best to implement the proposed separation distances. The Commission is proposing that the white space databases include information on the geographic areas and frequency bands where 600 MHz Band licensees have commenced operation. This information will be used to ensure that white space devices operate sufficiently far outside a licensee's service area to prevent harmful interference, and could also be used to ensure that wireless microphones operate sufficiently far outside a licensee's service area. Is there a need to require unlicensed wireless microphone users to check a database to ensure that they are outside a wireless licensee's service area, or are the general non-interference requirements described in the *Incentive Auction R&O* sufficient to protect 600 MHz Band licensees? Wireless microphone users would most likely access the databases through an Internet connection separate from the microphone since, during the post-auction transition period, users will likely continue to use microphones certified under current part 74 rules which are not designed to access the white space databases. How often should unlicensed wireless microphone users be required to check the database to determine whether a licensee has commenced operation? Should there be a time limit on how far in advance of an event a wireless microphone user can check the database? Are the timing intervals that we propose below for white space devices appropriate for wireless microphones to check for 600 MHz licensees that have commenced operation? Would the white spaces database administrators have to make any changes to their databases to allow unlicensed wireless microphone users to check whether they comply with the proposed separation distances? If so, what costs would be incurred and who would pay the costs? If any commenters believe the general non-interference requirements described in the *Incentive Auction R&O* are sufficient to protect 600 MHz Band licensees during the post-auction transition period, they should explain how interference would be resolved, by whom, and what mechanism would be used to identify interference sources.

C. White Spaces Databases

1. Expanding Location/Frequency Information in Database

a. WMTS

150. Authorized health care providers are authorized by rule to operate transmitters in the WMTS. Although the Commission does not issue individual licenses in this service, it does require that authorized health care providers that use WMTS devices must register the devices with a Commission-designated frequency coordinator prior to operation. The registration program assists users in meeting their obligation to cooperate in selecting and using frequencies to reduce the potential for interference with each other or co-primary RAS operations. ASHE/AHA, the Commission-designated WMTS frequency coordinator, has contracted with Comsearch to develop and maintain the WMTS database. WMTS users pay fees to ASHE/AHA and Comsearch to register their systems.

151. Some of the information already in the WMTS database, *e.g.,* the geographic coordinates of the transmitters operating on Channel 37, is the same type of information needed to protect the WMTS from interference by white space devices operating on channel 37 and in the adjacent bands, which would be either three megahertz guard bands or channels 36/38, depending on the outcome of the incentive auction. Specifically, we propose to include in the white spaces databases the following information obtained from the WMTS database for each WMTS device registration on channel 37:

(1) Frequency of operation (*i.e.,* channel 37),

(2) Geographic coordinates of transmitters, and

(3) Cross reference to the registration in the WMTS database (*e.g.,* record number).

152. The Commission believes that the number of WMTS transmitters at a location is not needed by the white spaces database since a white space device would have to meet the same distance separation requirements whether there is a single or many WMTS transmitters at a health care facility. We propose to require that a record for a WMTS operating location in the white spaces database include a cross reference to the corresponding information in the WMTS database, such a unique record identification number. The Commission believes that this requirement is necessary because the WMTS does not require individual licensing, so there are no call signs that could be used to cross-reference information between databases. Since it is only proposing to require the minimum information in the white spaces database necessary to determine if a device meets the required separation criteria from WMTS operating locations, we need to be able to reference the more detailed information in the WMTS database if there are questions concerning data accuracy or if interference occurs.

153. The Commission believes that using data from the WMTS database in the white space databases is preferable to requiring authorized health care providers to register in both databases. A duplicative registration requirement would be burdensome for WMTS users, could result in discrepancies in the data in both databases, and could delay populating the white space databases with the information necessary to protect WMTS users. The Commission also recognizes concerns raised by parties in the incentive auction proceeding that information in the WMTS database may be missing or imprecise. For example, although location information in the WMTS database may be sufficient for WMTS coordination purposes, that information may need to be updated before it could be used by the white space databases to determine interference protection distances. The Wireless Telecommunications Bureau (WTB), under delegated authority to oversee the WMTS coordinator and in conjunction with OET which has delegated authority to oversee the white spaces database administrators, would work with ASHE/AHA to accomplish this task under the terms of the MOU it has executed with ASHE/AHA for this purpose. OET also would work with ASHE/AHA and Comsearch to develop procedures to transfer the necessary information to the white spaces databases in a compatible format. The Commission emphasizes that under the current rules, all parties that operate WMTS equipment are already required to register with the WMTS coordinator. OET plans to work with ASHE/AHA and other parties as necessary to remind hospitals and other health care providers that use WMTS equipment of their obligation to register with the designated frequency coordinator and to ensure that such registration information is accurate.

154. The Commission seeks comment on these proposals. In particular, it seeks comment on the use of information from the WMTS database to protect the WMTS in the white spaces databases. Is the information we

proposed for inclusion in the white spaces database adequate, or is additional information necessary? What steps would ASHE/AHA and Comsearch have to take to modify the data in the WMTS database or the database functions to transfer data to the white spaces databases on a regular basis? How long would these modifications take, what costs would be incurred, and how would those costs be recovered? Are there any steps we can take to ensure the accuracy of the WMTS information? For example, could we allow the specification of multiple points to define a bounded area around a large facility that uses the WMTS as opposed to specifying a single point? If so, how could that be accomplished? Should we require ASHE/AHA to add more detailed location information to its database that would be transferred to the white spaces databases?

b. Radio Astronomy Service (RAS)

155. The current white space rules list the locations of 14 radio astronomy sites and require that all fixed and personal/portable devices operate at least 2.4 kilometers away from them. The 12 locations where the RAS receives on channel 37, specifically, the Arecibo Observatory, the Green Bank Telescope, and the ten sites that comprise the VLBA, are included in this list. Therefore, these locations are already in the white spaces database since they are protected under the current rules. However, the required 2.4 kilometer separation distance from these sites was based on the assumption that white space devices do not operate on channel 37. The Commission is proposing to allow white space device operation on channel 37, and proposing protection criteria for the RAS receive sites that receive channel 37 to protect them from interference. The white spaces database administrators would need to make two changes to their systems as a result of the proposed rules. First, they would have to require that white space devices meet separation distances greater than 2.4 kilometers from the ten VLBA sites. Second, they would have to include information on the quiet zones at Green Bank and the islands of Puerto Rico where white space devices may not operate. The Commission seeks comment on whether any other changes to the database would be required.

156. The other two RAS sites listed in § 15.712(h)(3) (the Allen Telescope Array and the Very Large Array) do not receive signals in the TV bands or the 600 MHz Band. The Commission is therefore proposing to delete them from the list of sites in this section. The Commission seeks comment on this proposal.

c. 600 MHz Band Services

157. In the *Incentive Auction R&O,* the Commission decided to permit the continued operation of white space devices on repurposed spectrum except in those areas in which a 600 MHz Band licensee commences operations. Recognizing that new licensees would likely commence operations at different places within their licensed service area at different times depending on their business plans and other factors, the Commission concluded that since white space devices can operate only on channels identified in the white spaces databases, these databases can serve to ensure that unlicensed operations will no longer occur on a channel on which a licensee has commenced operations. It stated that when a 600 MHz Band licensee plans to commence operations on frequencies that include channels available for unlicensed operations under the rules for white space devices, that licensee can notify any of the white spaces database administrators when and where it plans to commence operations. The Commission noted that, as an example, the white spaces databases could include the coordinates of four corners of a polygon that corresponds to the area where the 600 MHz Band licensee has commenced operations, and thus prevent operation of white space devices on the channel(s) used by the licensee within the defined area.

158. The Commission proposes to require that TV bands database administrators store information on the locations where 600 MHz Band licensees commence operations in a similar fashion to the example that the Commission discussed in the *Incentive Auction R&O.* Specifically, it proposes that the database administrators allow 600 MHz band licensees to enter the coordinates of at least eight points representing the corners of a polygon of the minimum size necessary to encompass all base stations within the area where a licensee is commencing operations, as well as the frequencies that a licensee will use in the specified area. The white spaces databases will use this information along with the protection criteria proposed in this NPRM to ensure that white space devices operate at a sufficient distance outside the border of the defined polygon to prevent interference to wireless services. The Commission is proposing to base the size of the polygon on the minimum size necessary to encompass base stations, since the proposed protection criteria for both wireless uplinks and downlinks are based on a minimum distance from base stations.

159. The Commission proposes that wireless licensees specify a polygon with a minimum of eight sides rather than four as the Commission previously suggested, and that a TV bands database be capable of accepting up to 120 points to delineate the wireless carrier's area of operation. This is the maximum number of points that a licensee may enter when partitioning a license area. This approach would provide wireless carriers with sufficient flexibility to describe different areas of operation. They could enter the coordinates of multiple polygons in cases where it plans to commence service in multiple non-contiguous areas. They also could specify shapes more complex than an eight-sided polygon to designate an area that includes irregular boundaries, such as PEA boundaries so that the protected area in the database stops at the edge of a carrier's licensed area.

160. The Commission seeks comment on these proposals. In particular, it seeks comment on whether a polygon with a minimum of eight sides is the appropriate method for defining the area where a licensee has commenced service. The Commission also seeks comment on whether it is necessary to allow for polygons with up to 120 sides. Would such a requirement be difficult for the database administrators to implement? The Commission further seeks comment on how the database should handle situations where a licensee is providing service up to the boundary of its licensed PEA. Should the database contain information on PEA boundaries so a licensee does not need to enter them? How difficult would it be for the database administrators to add that capability?

161. The Commission proposes that a 600 MHz Band licensee enter the date it plans to commence operations when it registers a polygonal area and operating frequencies with the TV bands database. It also proposes that the white space database administrators provide to the other database administrators on a daily basis the data registered by 600 MHz licensees, as they do for other services. Requiring the database to include the date for commencing operations will allow a licensee to define its operations area well in advance without limiting the ability of white space devices to operate until the actual date when the 600 MHz wireless licensee commences operation. The database will disregard the registration information prior to the service commencement date when determining which channels are available for white

space devices. Some licensees may not wish to make available details of their intended plans far in advance, and they could register their information closer to the actual date when they intend to commence operations. In doing so, they should keep in mind the time period needed for the white space databases to share information and the frequency with which white space devices are required to check for available channels.

d. Private Land Mobile Radio Service (PLMRS)

162. The Commission is proposing to modify the information required to be included in the white spaces databases for PLMRS/CMRS base station operations located more than 80 kilometers from the geographic centers of the 13 metropolitan areas defined in § 90.303(a) of the rules (*e.g.,* in accordance with a waiver). Section 15.713(h)(4) currently requires that the database include the transmitter location, effective radiated power, antenna height above ground and average terrain, and call sign for each PLMRS/CMRS base station. These stations are protected to a distance of 54 kilometers from co-channel white space devices, and 51 kilometers from adjacent channel white space devices. However, § 15.713(h)(4) does not require the database to include the TV channel number on which the PLMRS/CMRS station operates, which is information that needs to be included in the database to determine when a station needs protection. In addition, there does not appear to be any need to include the effective radiated power or antenna heights above ground and average terrain for each base station in the database. The protection criteria for base station is based on a geographic separation from the transmitter location, and the power and antenna height information are not necessary for the database to calculate the separation distance. Accordingly, the Commission proposes to modify § 15.713(h)(4) to require the TV bands database to include the TV channel number on which a PLMRS/CMRS base station operates, and to remove the requirement to include effective radiated power and antenna height information. The Commission seeks comment on this proposal.

e. Canadian and Mexican Stations Information

163. Because white space devices operate in the same frequency bands and on the same channels as TV stations in Canada and Mexico, the Commission is sensitive to the need to avoid causing harmful interference to TV broadcast operations in those countries. To this end, we committed to discussing with Canada and Mexico how we could include in our white space databases information on Canadian TV stations in the border areas that need to be protected. Currently, the Commission receives this information from Canada and passes it on to our white space database administrators who protect these locations. The Commission is discussing with Canada, which is moving ahead with its own program to permit white space devices on vacant TV channels, how best to have the Canadian and U.S. database administrators share information about stations in each country that need to be protected in the border areas. Some of these facilities may be receive sites that are not listed in Commission or Canadian government licensing databases, and the operators of the receive sites directly register their location information with the databases. The Commission seeks comment on how best to accomplish this objective. Should we require our database administrators to share this information directly with Canadian database administrators, or should the Commission be the conduit for passing this information to the Canadian database administrators?

2. Changes to Database Procedures

a. Wireless Microphones

164. Under the current rules, part 74 licensees operating Low Power Auxiliary Service (LPAS) equipment, including wireless microphones, may register their operating locations, channels and times in the white spaces database. The white spaces database protects these registered locations by requiring fixed devices to operate at least one kilometer from them and requiring personal/portable devices to operate at least 400 meters from them. Licensees may register their information directly with any one of the designated white space database administrators, and the information is then shared with all the other database administrators. In addition, parties operating large numbers of wireless microphones on an unlicensed basis are also allowed to register their operating locations in the white spaces database under certain circumstances. These registered locations are given the same protection from white space devices as licensed LPAS operations. Registration of unlicensed wireless microphones is limited to venues of events and productions and shows that use large numbers of microphones that cannot be accommodated in the two reserved channels and other channels that are not available for use by white space devices at a specific location.

165. The Commission proposes to eliminate the part 15 rule that permits unlicensed wireless microphone users to register the operating locations, channels and times in the white spaces databases to protect these operations from possible interference from white space devices. Thus, unlicensed wireless microphones would no longer be permitted to register their operations in the TV bands, as well as in the 600 MHz Band Plan guard bands or duplex gap. The Commission seeks comment on this proposal.

166. The Commission makes this proposal in part due to our recent decision to adopt the *TV Bands Wireless Microphones Second R&O,* 79 FR 40680 (July 14, 2014), in which we expanded eligibility for part 74 LPAS licenses to include professional sound companies and the owners and operators of large venues that routinely use 50 or more wireless microphones, and to permit these eligible entities to register directly in the TV bands database, provided that they obtain a license. The Commission notes that the goal in both the *TV Bands Wireless Microphones Second R&O* and in the *TV White Spaces Second MO&O,* 75 FR 75814 (December 6, 2010), in which the Commission adopted rules permitting unlicensed users to register in the TV bands database, was to ensure that entities requiring a large number of wireless microphones are able to register in the TV bands database. Commenters should address the extent to which this decision to expand license eligibility in the *TV Bands Wireless Microphone Second R&O* obviates the need for unlicensed wireless microphone users at ''venues of events and productions/shows that use large numbers of wireless microphones'' to register in the TV bands database.

167. The Commission also makes this proposal in part because in this NPRM we are proposing other ways that unlicensed microphones would operate on an equal basis with white space devices in the TV bands, the 600 MHz guard bands, and the portion of the duplex gap where we would allow unlicensed operation. For example, we propose technical rules (*e.g.,* power limits) for unlicensed microphones that are similar to those applicable to white space devices, thus reducing the potential for interference between these different uses. The Commission also proposes that unlicensed wireless microphones operating in the 600 MHz Band guard bands and duplex gap must contact the white spaces databases prior to operation to ensure that their

intended operating frequencies are available for unlicensed wireless microphones at the location where they will be used. Under the part 15 rules the Commission proposes to adopt, unlicensed wireless microphones, would operate under the same general conditions of operation as white space devices, meaning they may not cause interference to authorized services and must accept any interference received, including interference from other unlicensed devices.

b. White Space Device Re-Check Interval and Databases' Sharing of Registration Information

168. White space devices are required to re-check the database at least once per day to obtain the list of available TV channels at the location where the device operates. If a device is unable to make contact with the database on any given day, it may continue to operate until 11:59 p.m. on the following day, at which time it must cease operation until it re-establishes contact with the database. The Commission established these timeframes because most protected services listed in its databases do not change on a frequent basis. Further, since the Commission provides updated data to the white spaces database administrators only once every weekday, there is generally no need for white space devices to recheck the database more frequently than once per day.

169. The only protected use for which database information generally changes more frequently than once daily is wireless microphones. A wireless microphone user may register with a single white spaces database, and that database must then share the registration information with the other databases. The rules require such sharing to be done at least once daily, or more often as appropriate. The Commission established two reserved television channels where white space devices cannot operate to ensure that there would be spectrum available for wireless microphones used in applications such as electronic news gathering for which it is not possible to register the operating location in the database at least 24 hours in advance.

170. To ensure that wireless microphones used in applications such as electronic newsgathering receive protection in a timely manner, the Commission proposes two improvements—an increase in the frequency at which white space devices must re-check the database, and a limit on the time required for an LPAS registration made in one white spaces database to appear in all other white spaces databases. Specifically, it proposes to amend §§ 15.711(b)(3)(i) and 15.711(b)(3)(ii) of the rules to require fixed and Mode II personal/portable white space devices to re-check the database at time intervals not to exceed 20 minutes. The Commission also proposes to eliminate § 15.711(b)(3)(iii) which allows a white space device to continue operating until 11:59 p.m. on the following day if it cannot establish contact with the database. The Commission proposes to amend § 15.715(l) of the rules to require database administrators to share registration information between databases within ten minutes. The effect of these two proposals will be to ensure that a white space device ceases operation on a channel used by a wireless microphone within 30 minutes after a new registration is entered into the database. This 30 minute time interval is consistent with previous requests by NAB and Shure.

171. The Commission previously considered and rejected requests by wireless microphone manufacturers and users to establish a shorter re-check interval than the current 24 hours specified in the rules. In rejecting these requests, the Commission noted the steps it had taken to ensure that adequate spectrum in the TV bands remains available for licensed itinerant wireless microphone users by prohibiting personal/portable devices from operating below channel 21, designating two channels in each market from among channels 14–51 where white space devices cannot operate, and prohibiting fixed devices from operating adjacent to occupied television channels.

172. It is now appropriate to revisit the Commission's earlier decision that retained a 24-hour database re-check interval. In the *Incentive Auction R&O,* the Commission decided to no longer designate two vacant television channels exclusively for wireless microphone use. In making this change, the Commission stated that it also planned to make significant improvements to the white spaces databases to help address the concerns of wireless microphone users and accommodate their needs for access to available unused television channels, free from interference from unlicensed devices. There are now multiple white spaces databases in operation, and our experience with them has demonstrated that a channel re-check can be done very rapidly, so it does not appear that more frequent database checks would be unduly burdensome.

173. The Commission seeks comment on our proposals. In particular, it seeks comment on whether 20 minutes is an appropriate re-check interval, or whether the interval should be longer or shorter. The Commission also seeks comment on how a white space device should respond in the event that it cannot contact a database at the specified re-check interval. Should the device simply be required to cease transmitting, or should it be permitted to operate for a longer time so it can retry contacting the database? How much more time should be permitted, if any?

174. In addition, the Commission seeks comment on the appropriateness of the proposed ten minute time limit for sharing information between databases. Section 15.715(l) requires the sharing of registration information for fixed devices and MVPD receive sites in addition to wireless microphones. We seek comment on whether there is a need to require faster sharing of these other types of registration information, or whether any new requirements should apply only to wireless microphones.

175. Sections 15.711(b)(3)(i) and (ii) require that a fixed or personal/portable white space device that accesses the database must obtain wireless microphone scheduling information for a 48 hour period beginning from the time that the device accesses the database for a list of channels. This requirement is necessary because a white space device is only required to access the database once every 24 hours, and it may continue to operate for an additional 24 hours if it is unable to contact the database. However, if we require white space devices to contact the database every 20 minutes, it appears that this 48 hour time period could be reduced. The Commission proposes to require that a white space device must obtain wireless microphone scheduling information for a period of 60 minutes beginning from the last time it accesses a database. The Commission seeks comment on this proposal.

176. Finally, the Commission believes that these proposals, if adopted, should provide assurance to wireless microphone users that they will be able to access channels when and where they need them on short NPRM, without having to reserve multiple channels for every day/all day over extensive time periods. On several occasions we have seen microphone registrations that have been abusive of our rules and their intent to provide a fair opportunity for all microphone and white space device users to access available channels and make the most efficient use of spectrum. The Commission seeks comment on

whether there are other steps it should take to curb such abusive practices.

c. Database Registration and Fees

177. Under the current part 15 rules, fixed white space devices must register with the white space databases, providing the geographic coordinates, antenna height and certain identifying information. The Commission proposes to clarify its rules to ensure that fixed white space devices register with the databases if they would operate not only in TV bands but also in the repurposed 600 MHz Band, the guard bands and duplex gap, and Channel 37. The Commission also proposes to modify our rule that permits the white spaces database administrators to charge a fee for providing lists of available channels to white space devices and to register fixed white space devices to clearly state that this rule provision applies to white space devices that would operate in the TV bands, the repurposed 600 MHz Band, the 600 MHz guard bands, including the duplex gap, and Channel 37. The Commission also proposes that, if it adopts the proposal in this NPRM that unlicensed wireless microphones operating in the 600 MHz guard bands and duplex gap must contact the white spaces databases to identify operating frequencies available for their use, the database administrators may charge a fee for providing this information. The Commission seeks comment on these proposals.

178. The Commission permits the database administrators to assess fees to support the creation and operation of the databases, and these fees may be imposed on the operators of the white space devices in order to access the database and/or on the manufacturers of the white space devices. The Commission believes that both white space devices and unlicensed wireless microphones in the 600 MHz guard bands and duplex gap should be equally responsible for supporting the ongoing operation of the databases. Both types of uses benefit equally from the information provided by the databases. Should wireless microphone users also register their devices in the white space databases? Should database administrators assess a fee for microphone registration, as they do with fixed white space devices? Would a registration program facilitate the assessment of fees for obtaining channel lists? Commenters should address the feasibility of assessing database fees on unlicensed wireless microphone operators or manufacturers.

179. Regarding the registration of fixed white space devices in the white space databases, the Commission has stated that devices that do not check the database for three months to update their channel lists will be removed from the databases, but it did not codify this requirement. Fixed devices that are re-registered later would be subject to a new registration fee. The Commission seeks comment on whether it should continue this requirement, and whether it should apply to wireless microphones if we adopt a similar registration requirement for them. What purpose is served by removing a fixed device registration if it has not updated its channel list over a certain period of time? In this NPRM, the Commission is proposing to significantly increase the frequency for white space devices to re-check the database for a list of available channels. If the Commission continues this requirement, is a three month inactive period appropriate?

D. Equipment Certification and Marketing

180. Most part 15 intentional radiators, including white space devices and wireless microphones, must be authorized through the certification procedure before they can be imported into or marketed within the United States. Part 74 wireless microphones must also be authorized through the certification procedure. This procedure requires the filing of an application with either the Commission or a designated Telecommunications Certification Body (TCB) that includes test data demonstrating that the device complies with the appropriate technical rules. A grant of equipment certification does not normally specify an importation or marketing cutoff date, so it remains valid indefinitely unless revoked or withdrawn, rescinded, surrendered, or a termination date is otherwise established by the Commission.

181. The Commission is proposing rule changes in this NPRM that would give greater flexibility for fixed and personal/portable white space device operation in the TV bands. The majority of these changes are permissive, meaning that manufacturers of approved white space devices are not required to incorporate them into their equipment. However, the proposed requirement for white space devices to re-check a database at more frequent intervals would require changes to previously approved devices. In addition, the Commission is proposing to adopt rules for unlicensed wireless microphones that operate in the TV bands and for unlicensed devices and for licensed and unlicensed wireless microphones that operate in the guard bands and duplex gap. These devices will be affected by the transition provisions adopted in the *Incentive Auction R&O.* The Commission addresses certification, marketing and operational requirements for white space devices and unlicensed wireless microphones below.

Fixed and Personal/Portable Devices

182. Our proposal to require fixed and Mode II personal/portable devices to check the database more frequently and to obtain scheduling information for wireless microphones over a shorter time period would require changes to devices that were previously approved, since the frequency of checking the database is a function of a device. The Commission believes that this change can be implemented with a minor software update, so only short transition time periods are necessary. Accordingly, the Commission proposes to require that devices for which a certification application is filed beginning 30 days after the effective date of the rules comply with the new re-check requirements. The Commission also proposes to require that within 90 days after the effective date of the rules, all white space devices imported and marketed within the United States must comply with the new re-check requirement, regardless of when they were certified. The Commission further proposes to require that white space devices that do not comply with the new re-check requirements must cease operating within 180 days of the effective date of the rules. The Commission seeks comment on these proposals.

Wireless Microphones

183. All wireless microphones that now operate in the TV bands are certified as compliant with part 74, subpart H of the Commission's rules. The Commission decided in the *Incentive Auction R&O* that all wireless microphones that operate in the portion of the TV bands that will be repurposed for licensed wireless services may continue to operate in that spectrum during the post-auction transition period but must cease those operations no later than 39 months after release of the *Channel Reassignment Public Notice.* At the end of this post-auction transition period, licensed microphones will be permitted to operate in a portion of the duplex gap, and unlicensed wireless microphones will be permitted to operate in the guard bands and duplex gap.

184. Because of these future changes in the permitted operating frequency range for wireless microphones, plus the rule changes for these devices that the Commission proposes in this NPRM and in the Wireless Microphone NPRM, we

need to establish cutoff dates for the certification, manufacturing and marketing of wireless microphones in the guard bands and repurposed 600 MHz Band spectrum to ensure that manufacturers cease making and marketing equipment that cannot be legally used after a certain date. Cutoff dates will encourage manufacturers to concentrate on developing wireless microphones that operate in compliance with new parts 74 and 15 rules. Because similar technical requirements would apply to both licensed and unlicensed wireless microphones, the Commission proposes to apply to both the same transition rules for certification, manufacturing and marketing. This approach would be the least disruptive to wireless microphone manufacturers and users. In this NPRM, the Commission proposes rules for unlicensed wireless microphones; proposed rules for part 74 licensed wireless microphones are in the Wireless Microphone NPRM.

185. Although the Commission encourages wireless microphone manufacturers to come into compliance as soon as possible with new or revised technical rules, it may be preferable to have the transition period align as closely as possible with the post-auction transition schedule. Manufacturers and users will not know until after the auction which band plan will be in effect and where wireless microphones will be permitted to operate at the end of the post-auction transition period. The auction results will determine the size and frequency range of the 600 MHz Band guard bands, duplex gap, and repurposed spectrum. Our goal is to establish transition periods that are flexible and do not impose multiple re-certification requirements over a relatively short period of time.

186. Currently, unlicensed wireless microphones operate in the TV bands under part 15 of the Commission's rules pursuant to waivers. These devices must operate in compliance with certain technical requirements set forth in the *TV Bands Wireless Microphones R&O* and be certified under the applicable rules under part 74, subpart H. The waiver limits unlicensed wireless microphone operations to no greater than 50 milliwatts, but otherwise the technical requirements (*e.g.,* 200 kHz bandwidth limit) for their operations are the same as part 74 wireless microphones. Unlicensed microphone operations can continue in the core TV bands under this waiver until the effective date of final rules for their operation on an unlicensed basis under part 15. The rules the Commission proposes in this NPRM allows the certification of unlicensed wireless microphones that operate on channels 2–51, excluding channel 37. However, some portion of those channels will be repurposed for licensed wireless services. The Commission thus proposes that, after it adopts part 15 rules for unlicensed wireless microphone operation, the Commission continues to permit unlicensed wireless microphone users to operate part 74 wireless microphones in the TV bands under the waivers already in place until they must cease those operations no later than 39 months after release of the *Channel Reassignment Public Notice.* The Commission also proposes to accept applications to certify wireless microphones under part 15 rules as soon as those rules are effective, but not require such applications until after the incentive auction. The Commission seeks comment on these proposals.

187. The Commission proposes that parties may no longer submit applications to certify under part 15 wireless microphones that operate in repurposed TV spectrum beginning nine months after the release of the *Channel Reassignment Public Notice.* The Commission also proposes a manufacturing and marketing cutoff on wireless microphones that would not comply with the 600 MHz Band of 18 months after release of the *Channel Reassignment Public Notice.* The Commission seeks comment on these proposals. In particular, it seeks comment on the appropriateness of the proposed cutoff dates. Should we provide longer or shorter time periods? Should we also require that, in any event, parties may not submit applications to certify wireless microphones that operate in repurposed TV spectrum later than 24 months after the effective date of the service rules we adopt in this proceeding, and microphones that do not comply with the new rules may not be manufactured and marketed later than 33 months after the effective date of the service rules we adopt in this proceeding? Are any other requirements necessary, such as requiring advisory labeling or other information to the user about the operational cutoff date?

188. Unlike wireless microphones operating in the repurposed 600 MHz Band, operation of unlicensed wireless microphones in the guard bands and duplex gap is not affected by the post-auction transition requirements. To ensure that we can distinguish which wireless microphones may be legally operated after the transition from those that cannot, we propose the following requirements. A wireless microphone that is certified to operate only in the guard bands and duplex gap may continue to be marketed and operated with no cutoff date. However, if a wireless microphone is certified to operate in any portion of the repurposed 600 MHz Band, the Commission proposes that it may no longer be marketed or operated after the specified cutoff dates, even if it could be tuned to operate outside the repurposed 600 MHz Band. This approach will allow use of the FCC identification number to identify which wireless microphones may be legally marketed and operated, rather than having to determine the precise frequency to which a specific wireless microphone is tuned, which may not be indicated on the device. The Commission seeks comment on this proposal.

Procedural Matters

189. As required by the Regulatory Flexibility Act of 1980, as amended (RFA),[1] the Commission has prepared this present Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in this *NPRM of Proposed Rule Making (NPRM).* Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on the *NPRM* provided in the item. The Commission will send a copy of the *NPRM,* including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).[2]

A. Need for, and Objectives of, the Proposed Rules

190. The *NPRM* proposes rules for unlicensed operations in the frequency bands that are now and will continue to be allocated and assigned to broadcast television services (TV bands), including fixed and personal/portable white space devices and unlicensed wireless microphones. Based on its experience with the development and deployment of white space devices in the TV bands, the Commission is considering changes to the part 15 rules that will allow for more robust service and efficient spectral use without increasing the risk of harmful interference to authorized users. The *NPRM* also proposes to codify rules for the operation of unlicensed wireless microphones in the TV bands.

[1] *See* 5 U.S.C. 603. The RFA, *see* 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. 857 (1996).

[2] *See* 5 U.S.C. 603(a).

191. The *NPRM* addresses issues that arise from the *Incentive Auction R&O* to repurpose a portion of the broadcast spectrum for new wireless services.[3] The 600 MHz Band Plan adopted in the *Incentive Auction R&O* provides new opportunities for unlicensed white space devices, unlicensed wireless microphones and wireless microphones licensed under part 74. The *NPRM* proposes rules for their operation that will protect licensed services as spectrum is repurposed to introduce new wireless services.

B. Legal Basis

192. The proposed action is taken pursuant to Sections 4(i), 301, 302, 303(e), 303(f), 303(r), 304 and 307 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 301, 302, 303(e), 303(f), 303(r), 304 and 307.

C. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

193. 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, if adopted.[4] The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.''[5] In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.[6] 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 Small Business Administration (SBA).[7]

194. *Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing.* The Census Bureau defines this category as follows: ''This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: Transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment.''[8] The SBA has developed a small business size standard for Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing, which is: All such firms having 750 or fewer employees. According to Census Bureau data for 2007, there were a total of 939 establishments in this category that operated for part or all of the entire year. Of this total, 912 had less than 500 employees and 17 had more than 1000 employees.[9] Thus, under that size standard, the majority of firms can be considered small.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

195. White space devices are unlicensed devices that operate in the TV bands at locations where frequencies are not in use by licensed services. These devices may be either fixed or personal/portable. Fixed devices may operate at power levels up to four watts, and personal/portable devices operate at up to 100 milliwatts, if they are outside the service contours of adjacent channel TV stations. Personal/portable devices may operate with 40 milliwatts if they are within the service contour of an adjacent channel TV station. White space devices are not permitted to operate on channel 37 (608–614 MHz), which is use by the Radio Astronomy Service (RAS) and Wireless Medical Telemetry Service (WMTS). To prevent harmful interference to broadcast television stations and other authorized users of these bands, white space devices must obtain a list of available TV channels that may be used at their location from databases administered by private entities selected by the Commission.

196. Wireless microphones also operate in the TV bands. Certain entities may be issued licenses under subpart H of part 74 of the rules to operate low power auxiliary stations in the TV bands. Because the operators of part 74 wireless microphones are licensed, they may register the times and locations of their operation in the white spaces databases to obtain interference protection from co-channel white space devices. The Commission also allows the operation of part 74 certified wireless microphones in the VHF and UHF TV bands on an unlicensed basis under a waiver of the part 15 rules granted in the 2010 *TV Bands Wireless Microphones R&O and Further NPRM.*[10] Operators of unlicensed wireless microphones are generally not permitted to register in the TV bands database, but parties operating large numbers of wireless microphones on an unlicensed basis at venues of events and productions/shows may register in the TV bands database if they meet certain criteria specified in the rules and obtain Commission approval to do so.

197. In the *Incentive Auction R&O,* the Commission decided to repurpose a portion of the UHF TV spectrum for licensed wireless services (the ''600 MHz Band''). The Commission's band plan provides for a guard band between television spectrum and 600 MHz downlink services, a guard band between 600 MHz uplink and downlink services (a duplex gap), and guard bands between 600 MHz downlink services and channel 37. In the TV bands that are repurposed for wireless services, the Commission decided to allow white space devices to continue operating indefinitely in areas where a 600 MHz Band licensee has not commenced operations, and to allow wireless microphones to operate for 39 months after release of a public NPRM announcing channel reassignments as a result of the incentive auction.

198. Most RF transmitting equipment, including white space devices and wireless microphones, must be authorized through the certification procedure. Certification is an equipment authorization issued by the Commission or by a designated TCB based on an application and test data submitted by the responsible party (*e.g.,* the manufacturer or importer).[11] The NPRM

[3] *See Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions,* GN Docket No. 12–268, Report and Order, 29 FCC Rcd 6567 (2014) (*Incentive Auction R&O*).

[4] *See* 5 U.S.C. 603(b)(3).

[5] *See* 5 U.S.C. 601(6).

[6] *See* 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**.''

[7] *See* 15 U.S.C. 632.

[8] The NAICS Code for this service 334220. *See* 13 CFR 121/201. *See also http://factfinder.census.gov/servlet/IBQTable?_bm=y&-fds_name=EC0700A1&-geo_id=&-_skip=300&-ds_name=EC0731SG2&-_lang=en*

[9] *See http://factfinder.census.gov/servlet/IBQTable?_bm=y&-geo_id=&-fds_name=EC0700A1&-_skip=4500&-ds_name=EC0731SG3&-_lang=en*

[10] *See* Revisions to Rules Authorizing the Operation of Low Power Auxiliary Stations in the 698–806 MHz Band, WT Docket No. 08–166, Public Interest Spectrum Coalition, Petition for Rulemaking Regarding Low Power Auxiliary Stations, Including Wireless Microphones, and the Digital Television Transition, WT Docket No. 08–167, Amendment of Parts 15, 74 and 90 of the Commission's Rules Regarding Low Power Auxiliary Stations, Including Wireless Microphones, ET Docket No. 10–24, *Report and Order and Further NPRM of Proposed Rulemaking,* 25 FCC Rcd 643, 682–87, para. 81–90 (2010).

[11] *See* 47 CFR 2.907. The Commission or a TCB may test a sample of a device to verify that it

Continued

does not propose to change the authorization procedure for white space devices and wireless microphones, but it does propose to establish new technical requirements or modify existing technical requirements for white space devices and wireless microphones.

199. The NPRM proposes to establish the following new and changed compliance requirements for white space devices, unlicensed wireless microphones and licensed wireless microphones:

White Space Devices That Operate in the TV Bands Remaining After the Incentive Auction and Channel Reassignment

- Allow personal/portable white space devices to operate on channels 14–20 where their operation is currently prohibited.
- Allow fixed white space devices to:
  - Operate at 40 milliwatts on channels adjacent to occupied TV channels.
  - Operate at 4 Watts where there are two contiguous vacant TV channels rather than three as the rules currently require.
  - Operate closer to a TV station contour when the operating power is reduced.

White Space Devices Operating in the 600 MHz Guard Bands, Duplex Gap and Channel 37

- Allow fixed and personal/portable devices to operate at 40 milliwatts in the guard bands and the upper six megahertz portion of the duplex gap.
- Allow white space devices to operate on channel 37, subject to minimum separation distances enforced by the white spaces databases to protect the WMTS and RAS.
- Require that fixed and personal/portable devices operating in the repurposed 600 MHz Band comply with minimum separation distances from the areas where part 27 licensees have commenced operations. This would be enforced by the white spaces databases.

Wireless Microphones

- Codify new part 15 rules for unlicensed wireless microphones in the TV bands. Wireless microphones operating on an unlicensed basis are currently certified under the part 74 rules.
- Allow unlicensed wireless microphones to operate at 20 milliwatts in the 600 MHz guard bands and the upper six megahertz portion of the duplex gap. Unlicensed wireless microphones would have to rely on the white spaces databases to ensure they are operating on channels available for their use.
- Allow licensed wireless microphones to operate at 20 milliwatts in the four megahertz portion of the duplex gap below the six megahertz portion used by white space devices and unlicensed wireless microphones.
- Require wireless microphones operating in the repurposed 600 MHz Band to comply with minimum separation distances from the areas where part 27 600 MHz Band licensees have commenced operations.

White Spaces Databases

- Expand the databases to include location/frequency information for additional licensed services such as the WMTS and part 27 600 MHz Band services.
- Require more frequent database re-checks by white space devices and faster database updates. This would enable wireless microphone users to register, on short NPRM, in the white spaces databases channels that would be protected from interference from white space devices.
- Eliminate registration in the white spaces databases of channels used by unlicensed wireless microphones for protection from white space devices.

Certification of White Space Devices and Wireless Microphones

- White space devices would have to meet the following timetable for compliance with the shorter database re-check interval: 30 days for new equipment certification, 90 days for equipment importation and marketing, 180 days for equipment operation.
- Wireless microphones in the repurposed TV spectrum would have to meet the following cutoff dates, which are from the release of the channel reassignment public notice: 9 months for equipment certification, 18 months for importing and marketing equipment (the 39 month date for ceasing operation in the band was decided in the *Incentive Auction R&O*).

E. Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered

200. The RFA requires an agency to describe any significant, specifically small business, alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): ''(1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.'' [12]

201. The rule changes proposed in the NPRM would give greater flexibility for fixed and personal/portable white space device operation. The majority of these changes are permissive, meaning that manufacturers of approved white space devices are not required to incorporate them into their equipment. However, the proposed requirement for white space devices to re-check a database at more frequent intervals would require changes to previously approved devices. We propose a transition period for equipment manufacturers and users to make the change. While we believe that only a short transition period is necessary, the NPRM seeks comment on whether the Commission should allow more time.

202. Licensed and unlicensed wireless microphones that operate in the TV bands will be affected by the transition provisions adopted in the *Incentive Auction R&O.* The NPRM proposes transition periods that we believe are reasonable to minimize the burden on wireless microphone manufacturers and users, while implementing the Commission's previous decision to transition users out of the repurposed TV spectrum within 39 months. Specifically, we propose to allow manufacturers a period of nine months after the final 600 MHz Band Plan is announced before they may no longer certify wireless microphones that operate in the repurposed TV spectrum, and a period of 18 months before they must cease marketing them. The Commission also proposes that parties operating wireless microphones on an unlicensed basis may continue to use part 74 certified wireless microphones rather than part 15 certified wireless microphones until the end of the 39 month transition to avoid users having to replace equipment more than once.

203. The NPRM proposes a number of changes that would require the white space database administrators to make changes to their systems. For example, the NPRM would require the database administrators to implement new

complies with the rules before granting approval for the equipment to be marketed. Examples of devices subject to certification include, but are not limited to, mobile phones; wireless local area networking equipment, remote control transmitters; land mobile radio transmitters; wireless medical telemetry transmitters; cordless telephones; and walkie-talkies.

[12] *See* 5 U.S.C. 603(c)(1) through (c)(4).

protection requirements for the WMTS and part 27 wireless licensees, and modified protection requirements for TV stations and the RAS. The NPRM seeks information on the costs and burdens the proposed changes would place on the database administrators, and how the database administrators could recoup their costs.

F. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

204. None.

205. Pursuant to Sections 1, 4(i), 7(a), 301, 303(f), 303(g), 303(r), 307(e) and 332 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 157(a), 301, 303(f), 303(g), 303(r), 307(e), and 332, this NPRM of Proposed Rule Making IS ADOPTED.

206. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, SHALL SEND a copy of this NPRM of Proposed Rule Making, including the Initial Regulatory Flexibility Analysis to the Chief Counsel for Advocacy of the Small Business Administration.

List of Subjects in 47 CFR Parts 15 and 74

Communications equipment, Radio, and Reporting and recordkeeping requirements.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

Proposed Rules

For the reasons set forth in the preamble, the Federal Communications Commission proposes to amend 47 CFR parts 15 and 74 as follows:

PART 15—RADIO FREQUENCY DEVICES

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

Authority: 47 U.S.C. 154, 302a, 303, 304, 307, 336, 544a, and 549.

■ 2. Section 15.37 is amended by adding paragraph (i) and paragraph (j) to read as follows:

§ 15.37 Transition provisions for compliance with the rules.

* * * * *

(i) Certification may no longer be obtained for wireless microphones that operate in the repurposed TV spectrum beginning nine months after release of the Channel Reassignment Public Notice issued pursuant to *Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions,* Report and Order, GN Docket No. 12–268 (FCC 14–50), 29 FCC 6567 (2014). Manufacturing and marketing of wireless microphones that operate in the repurposed TV spectrum must cease 18 months after release of the Channel Reassignment Public Notice, and operation of these wireless microphones must cease 39 months after release of the Channel Reassignment Public Notice.

(j) Fixed and Mode II personal/portable white space devices for which an application for certification is filed beginning [30 days after the effective date of the rules] must comply with the database re-check requirements in § 15.711(b)(3)(i) and (ii). Fixed and Mode II personal/portable white space devices that are marketed beginning [90 days after the effective date of the rule] must comply with these requirements. Previously approved white space devices that do not comply with these requirements must cease operating no later than [180 days after the effective date of the rules].

■ 3. Section 15.236 is added to read as follows:

§ 15.236 Operation of wireless microphones in the bands 54–72 MHz, 76–88 MHz, 174–216 MHz, 470–608 MHz and 614–698 MHz.

(a) *Definitions.* The following definitions apply in this section.

(1) *Wireless Microphone.* An intentional radiator that converts sound into electrical audio signals that are transmitted using radio signals to a receiver which converts the radio signals back into audio signals that are sent through a sound recording or amplifying system. Wireless microphones may be used for cue and control communications and synchronization of TV camera signals as defined in § 74.801 of this chapter. Wireless microphones do not include auditory assistance devices as defined in § 15.3(a).

(2) *600 MHz duplex gap.* An 11 megahertz guard band that separates wireless uplink and downlink frequencies within the 600 MHz Band as determined by the outcome of the auction conducted pursuant to *Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions,* Report and Order, GN Docket No. 12–268 (FCC 14–50), 29 FCC 6567 (2014).

(3) *600 MHz guard band.* Designated frequency bands within the 600 MHz Band that prevent interference between licensed services as determined by the outcome of the auction conducted pursuant to *Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions,* Report and Order, GN Docket No. 12–268 (FCC 14–50), 29 FCC 6567 (2014).

(4) *Repurposed 600 MHz Band.* Frequencies that will be reallocated and reassigned for part 27 600 MHz Band services as determined by the outcome of the auction conducted pursuant to *Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions,* Report and Order, GN Docket No. 12–268 (FCC 14–50), 29 FCC 6567 (2014).

(b) Operation under this section is limited to wireless microphones as defined in this section.

(c) *Operation is permitted in the following bands.*

(1) Channels allocated and assigned for broadcast television service.

(2) Television channels in the repurposed 600 MHz Band. Operation on these channels must cease no later than 39 months after release of the Channel Reassignment Public Notice issued pursuant to *Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions,* Report and Order, GN Docket No. 12–268 (FCC 14–50), 29 FCC 6567 (2014). Operation must cease immediately if harmful interference occurs to a 600 MHz Band licensee.

(3) The upper six megahertz segment of the 600 MHz Band duplex gap.

(4) The 600 MHz guard band between television and wireless downlink services, excluding the upper one megahertz segment.

(5) The 600 MHz guard bands adjacent to channel 37, excluding the one megahertz segments furthest from channel 37.

(6) Microphone operation in the frequencies identified in paragraphs (c)(3) through(5) of this section shall prior to operation rely on the white space databases in part 15, subpart H to determine that their intended operating frequencies are available for unlicensed wireless microphone operation at the location where they will be used.

(d) The unmodulated carrier power at the antenna input may not exceed the following values.

(1) In the bands allocated and assigned for broadcast television and in the repurposed 600 MHz Band: 50 mW

(2) In the 600 MHz Band guard bands including the duplex gap: 20 mW.

(e) Operation is limited to locations separated from licensed services by the following distances.

(1) Four kilometers outside the following protected service contours of co-channel TV stations.

Type of station	Protected contour		
	Channel	Contour (dBu)	Propagation curve
Analog: Class A TV, LPTV, translator and booster	Low VHF (2–6)	47	F(50,50)
	High VHF (7–13)	56	F(50,50)
	UHF (14–51)	64	F(50,50)
Digital: Full service TV, Class A TV, LPTV, translator and booster	Low VHF (2–6)	28	F(50,90)
	High VHF (7–13)	36	F(50,90)
	UHF (14–51)	41	F(50,90)

(2) The following distances outside of the area where a 600 MHz Band licensee has commenced operations.

Type of station	Separation distance in kilometers	
	Co-channel	Adjacent channel
Base	15	0.4
Mobile	35	31

(f) The operating frequency within a permissible band of operation as defined in paragraph (b) of this section must comply with the following requirements.

(1) The frequency selection shall be offset from the upper or lower band limits by 25 kHz or an integral multiple thereof.

(2) One or more adjacent 25 kHz segments within the assignable frequencies may be combined to form a channel whose maximum bandwidth shall not exceed 200 kHz. The operating bandwidth shall not exceed 200 kHz.

(3) The frequency tolerance of the carrier signal shall be maintained within +/− 0.005% of the operating frequency over a temperature variation of -20 degrees to +50 degrees C at normal supply voltage, and for a variation in the primary supply voltage from 85% to 115% of the rated supply voltage at a temperature of 20 degrees C. Battery operated equipment shall be tested using a new battery.

(g) Emissions within the band from one megahertz below to one megahertz above the carrier frequency shall comply with the emission mask in Section 8.3 of ETSI EN 300 422–1, *Electromagnetic compatibility and Radio spectrum Matters (ERM); Wireless microphones in the 25 MHz to 3 GHz frequency range; Part 1: Technical characteristics and methods of measurement.* Emissions outside this band shall comply with the limits in § 15.209.

■ 4. Revise the heading of subpart H to part 15 to read as follows:

Subpart H—White Space Devices

■ 5. Section 15.701 is revised to read as follows:

§ 15.701 Scope.

This subpart sets forth the regulations for unlicensed intentional radiators that operate on available channels in the frequency bands at 54–72 MHz (TV channels 2–4), 76–88 MHz (TV channels 5–6), 174–216 MHz (TV channels 7–13), and 470–698 MHz (TV channels 14–51).

■ 6. Section 15.703 is amended by revising paragraphs (a), (c), (i), (k), (l), (m), (n) and adding paragraphs, (o), (p), (q) and (r) to read as follows:

§ 15.703 Definitions.

(a) *Available channel.* A channel which is not being used by an authorized service at or near the same geographic location as an unlicensed device and is acceptable for use by the device under the provisions of this subpart.

* * * * *

(c) *Fixed device.* A device that transmits and/or receives radiocommunication signals at a specified fixed location. A fixed device may select channels for operation itself from a list of available channels provided by a white spaces database, and initiate and operate a network by sending enabling signals to one or more fixed devices and/or personal/portable devices.

* * * * *

(i) *Personal/portable device.* A device that transmits and/or receives radiocommunication signals on available channels at unspecified locations that may change.

* * * * *

(k) *Repurposed 600 MHz Band.* Frequencies that will be reallocated and reassigned for part 27 600 MHz Band services as determined by the outcome of the auction conducted pursuant to *Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions,* Report and Order, GN Docket No. 12–268 (FCC 14–50), 29 FCC 6567 (2014).

(l) *Sensing only device.* A personal/portable TVBD that uses spectrum sensing to determine a list of available channels. Sensing only devices may transmit on any available channels in the frequency bands 512–608 MHz (TV channels 21–36) and 614–698 MHz (TV channels 38–51).

(m) *Spectrum sensing.* A process whereby a TVBD monitors a television channel to detect whether the channel is occupied by a radio signal or signals from authorized services.

(n) *Television bands.* The portions of the broadcast television frequency bands at 54–72 MHz (TV channels 2–4), 76–88 MHz (TV channels 5–6), 174–216 MHz (TV channels 7–13), 470–608 MHz (channels 14–36) and 614–698 MHz (channels 38–51) that will be allocated and assigned to broadcast television licensees consistent with the outcome of the auction conducted pursuant to *Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions,* Report and Order, GN Docket No. 12–268 (FCC 14–50), 29 FCC 6567 (2014).

(o) *White space device.* An intentional radiator that operates in the television bands, the 600 MHz Band or on channel 37 accordance with the provisions of this subpart.

(p) *White spaces database.* A database system that maintains records of all authorized services in the television and 600 MHz frequency bands, is capable of determining the available channels as a specific geographic location and provides lists of available channels to unlicensed devices that have been certified under the Commission's equipment authorization procedures. White spaces databases that provide lists of available channels to unlicensed devices must receive approval by the Commission.

(q) *600 MHz duplex gap.* An 11 megahertz guard band that separates wireless uplink and downlink frequencies within the 600 MHz Band as determined by the outcome of the auction conducted pursuant to *Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions,* Report and Order, GN Docket No. 12–268 (FCC 14–50), 29 FCC 6567 (2014).

(r) *600 MHz guard band.* Designated frequency bands within the 600 MHz Band that prevent interference between licensed services as determined by the outcome of the auction conducted pursuant to *Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions,* Report and Order, GN Docket No. 12–268 (FCC 14–50), 29 FCC 6567 (2014).

■ 7. Section 15.707 is revised to read as follows:

§ 15.707 Permissible channels of operation.

(a)(1) Fixed and personal/portable white space devices may operate on available channels in the frequency bands 470–608 (TV channels 14–36), 512–608 MHz (TV channels 21–36) and 614–698 MHz (TV channels 38–51), subject to the interference protection requirements in §§ 15.711 and 15.712.

(2) Fixed and personal/portable devices may operate on frequencies in the repurposed 600 MHz Band in areas where part 27 600 MHz Band licensees have not commenced operations, as defined in part 27 of this chapter.

(b) Only fixed devices that communicate with other fixed devices may operate on available channels in the bands 54–72 MHz (TV channels 2–4), 76–88 MHz (TV channels 5 and 6) and 174–216 MHz (TV channels 7–13) subject to the interference protection requirements in §§ 15.711 and 15.712.

(c) Fixed and Mode II personal/portable devices shall operate only on available channels as identified in paragraphs (a) and (b) of this section and as determined by a white spaces database in accordance with the interference avoidance mechanisms of §§ 15.711 and 15.712.

(d) Mode I personal/portable devices shall operate only on available channels as identified in paragraph (a)(1) of this section and provided from a fixed or Mode II device in accordance with § 15.711(b)(3)(iv).

(e) Fixed and personal/portable devices may operate in the upper six megahertz segment of the 600 MHz duplex gap.

(f) Fixed and personal/portable devices may operate in the 600 MHz guard band between television and wireless downlink services, excluding the upper three megahertz segment, provided this guard band is at least nine megahertz wide.

■ 8. Section 15.709 is amended by revising paragraphs (a) and (c) to read as follows:

§ 15.709 General technical requirements.

(a) *Power limits for white space devices.* (1) The maximum EIRP for fixed white space devices operating in the television bands and repurposed 600 MHz Band shall not exceed the following values:

(i) If the device complies with the minimum separation distances outside adjacent channel television service contours in § 15.712(a): four watts (36 dBm) per six megahertz of bandwidth on which the device operates.

(ii) If the device operates within a six megahertz band centered on the boundary between two available channels: four watts (36 dBm) per six megahertz of bandwidth on which the device operates.

(iii) If the device operates adjacent to an occupied television channel, *i.e.,* within its protected service contour: 40 mW (16 dBm) per six megahertz of bandwidth on which the device operates.

(2) The maximum EIRP for personal/portable white space devices operating in the television bands and repurposed 600 MHz Band shall not exceed the following values:

(i) If the device complies with the minimum separation distances outside adjacent channel television service contours in § 15.712(a): 100 mW (20 dBm) per six megahertz of bandwidth on which the device operates.

(ii) If the device operates adjacent to an occupied television channel, *i.e.,* within its protected service contour: 40 mW (16 dBm) per six megahertz of bandwidth on which the device operates.

(3) The maximum EIRP for fixed and personal/portable white space devices operating in the 600 MHz guard band and duplex gap shall not exceed 40 mW (16 dBm).

(4) The maximum EIRP for fixed white space devices operating on channel 37 shall not exceed the following values:

(i) If channels 36 and 38 are allocated and assigned for television broadcasting and the device complies with the minimum separation distances outside adjacent channel television service contours in § 15.712(a): four watts (36 dBm) per six megahertz of bandwidth on which the device operates.

(ii) If channels 36 and 38 are allocated and assigned for television broadcasting and the device operates within a six megahertz band centered on the boundary between channel 37 and an available adjacent channel: four watts (36 dBm) per six megahertz of bandwidth on which the device operates.

(iii) If channels 36 and 38 are allocated and assigned for television broadcasting and the device operates adjacent to an occupied television channel, *i.e.,* within its protected service contour, or if one or both of the adjacent bands are designated as 600 MHz guard bands: 40 mW (16 dBm) per six megahertz of bandwidth on which the device operates.

(5) Mode I personal/portable devices that operate on available channels provided by a Mode II device that operates within the protected service contour of an adjacent channel television station are limited to a maximum EIRP of 40 milliwatts (16 dBm) per six megahertz of bandwidth on which the device operates.

(6) Fixed devices with a four watt EIRP limit may operate closer to co-channel and adjacent channel television stations and other protected services at reduced power levels. The following table shows the power levels at which separation distances are defined. Devices operating at a particular EIRP level must comply with the limit on conducted power to the antenna. The power delivered to the transmitting antenna is the maximum conducted output power reduced by the signal loss experienced in the cable used to connect the transmitter to the transmit antenna. The conducted power limits are based on a maximum transmitting antenna gain of 6 dBi. If transmitting antennas of directional gain greater than 6 dBi are used, the maximum conducted output power shall be reduced by the amount in dB that the directional gain of the antenna exceeds 6 dBi. Operation is permitted at EIRP levels between the values in this table, provided the conducted power limit is interpolated between the values shown.

EIRP (6 MHz)	Conducted power limit (6 MHz)
16 dBm (40 mW)	10 dBm (10 mW).
20 dBm (100 mW)	14 dBm (25 mW).
24 dBm (250 mW)	18 dBm (63 mW).
28 dBm (625 mW)	22 dBm (158 mW).
32 dBm (1600 mW)	26 dBm (400 mW).
36 dBm (4000 mW)	30 dBm (1000 mW).

(7) Maximum conducted output power is the total transmit power over the occupied bandwidth delivered to all antennas and antenna elements averaged across all symbols in the signaling alphabet when the transmitter is operating at its maximum power control level. Power must be summed across all antennas and antenna elements. The average must not include any time intervals during which the transmitter is off or is transmitting at a reduced power level. If multiple modes of operation are possible (*e.g.,* alternative modulation methods), the maximum conducted output power is

the highest total transmit power occurring in any mode.

(8) White space devices shall incorporate transmit power control to limit their operating power to the minimum necessary for successful communication. Applicants for equipment certification shall include a description of a device's transmit power control feature mechanism.

(9) The power spectral density from a white space device shall not be greater than the following values when measured in any 100 kHz band during any time interval of continuous transmission.

(i) Fixed devices: The values shown in the following table. If transmitting antennas of directional gain greater than 6 dBi are used, the conducted power level shall be reduced by the amount in dB that the directional gain of the antenna exceeds 6 dBi. If the conducted power of the device is between two defined levels, then the PSD limit must be interpolated between the values shown.

Conducted power limit (6 MHz)	Conducted PSD limit (100 kHz)
10 dBm (10 mW)	−7.4 dBm.
14 dBm (25 mW)	−3.4 dBm.
18 dBm (63 mW)	0.6 dBm.
22 dBm (158 mW)	4.6 dBm.
26 dBm (400 mW)	8.6 dBm.
30 dBm (1000 mW)	12.6 dBm.

(ii) Personal/portable device operating at 40 mW: −1.4 dBm EIRP.

(iii) Sensing-only devices operating at 50 mW: −0.4 dBm EIRP.

(iv) Personal/portable devices operating at 100 mW: 2.6 dBm EIRP.

(10) White space devices shall incorporate adequate security measures to prevent the devices from accessing databases not approved by the FCC and to ensure that unauthorized parties cannot modify the device or configure its control features to operate in a manner inconsistent with the rules and protection criteria set forth in this subpart.

* * * * *

(c) *Emission limits for white space devices.* (1) In the six megahertz bands immediately adjacent to the channel or group of contiguous channels in which the device is operating, emissions from the device shall not exceed the following levels.

(i) Fixed devices: The values shown in the following table. If transmitting antennas of directional gain greater than 6 dBi are used, the conducted power level shall be reduced by the amount in dB that the directional gain of the antenna exceeds 6 dBi. If a device operates between two defined power levels, it must comply with the limit for the higher power level.

Conducted power limit (6 MHz)	Adjacent channel emission limit (100 kHz)
10 dBm (10 mW)	−62.8 dBm.
14 dBm (25 mW)	−58.8 dBm.
18 dBm (63 mW)	−54.8 dBm.
22 dBm (158 mW)	−50.8 dBm.
26 dBm (400 mW)	−46.8 dBm.
30 dBm (1000 mW)	−42.8 dBm.

(ii) Personal/portable devices operating at 40 mW EIRP: −56.8 dBm EIRP.

(iii) Sensing-only devices operating at 50 mW EIRP: −55.8 dBm EIRP.

(iv) Personal/portable devices operating at 100 mW: −52.8 dBm EIRP.

(2) Emission measurements in the adjacent bands shall be performed using a minimum resolution bandwidth of 100 kHz with an average detector. A narrower resolution bandwidth may be employed near the band edge, when necessary, provided the measured energy is integrated to show the total power over 100 kHz.

(3) At frequencies beyond the six megahertz bands immediately adjacent to the channel or group of contiguous channels in which the device is operating, the radiated emissions from devices shall meet the requirements of § 15.209. If a white space device transmits on multiple non-contiguous channels simultaneously, it must comply with the adjacent channel emission limits in the six megahertz bands above and below each of the single channels or channel groups used by the white space device, and the requirements of § 15.209 beyond these six megahertz bands.

(4) White space devices connected to the AC power line are required to comply with the conducted limits set forth in § 15.207.

* * * * *

■ 9. Section 15.711 is amended by revising the introductory text and paragraphs (a), (b)(3)(i) and (ii), removing and reserving paragraph (b)(3)(iii), and revising paragraph (b)(3)(v) to read as follows:

§ 15.711 Interference avoidance methods.

Except as provided in § 15.717, television channel availability for a white space device is determined based on the geo-location and database access method described in paragraphs (a) and (b) of this section.

(a) *Geo-location and database access.* A white space device shall rely on the geo-location and database access mechanism to identify available channels consistent with the interference protection requirements of § 15.712. Such protection will be provided for the following authorized and unlicensed services: Digital television stations, digital and analog Class A, low power, translator and booster stations; translator receive operations; fixed broadcast auxiliary service links; private land mobile service/commercial radio service (PLMRS/CMRS) operations; offshore radiotelephone service; low power auxiliary services authorized pursuant to §§ 74.801 through 74.882 of this chapter, including licensed wireless microphones; MVPD receive sites; wireless medical telemetry service (WMTS); radio astronomy service (RAS) and part 27 600 MHz Band licensees where they have commenced operations. In addition, protection shall be provided in border areas near Canada and Mexico in accordance with § 15.712(g).

(b) * * *

(3)(i) Fixed devices must access a white spaces database over the Internet to determine the channels that are available at their geographic coordinates, taking into consideration the fixed device's antenna height and operating power, prior to their initial service transmission at a given location. Operation is permitted only on channels that are indicated in the database as being available for their use. Fixed devices shall access the database at least once every 20 minutes to verify that the operating channels continue to remain available. Operation on a channel must cease immediately if the database indicates that the channel is no longer available. Fixed devices must adjust their use of channels in accordance with channel availability schedule information provided by their database for the 60 minute period beginning at the time of the device last accessed the database for a list of available channels.

(ii) Mode II personal/portable devices must access a white spaces database over the internet to determine the channels that are available at their geographic coordinates, taking into account the device's operating power, prior to their initial service transmission at a given location. Operation is permitted only on channels that are indicated in the database as being available for personal/portable devices. A Mode II device must access the database for a list of available channels each time it is activated from a power-off condition and re-check its location and the database for available channels if it changes location during operation by more than 100 meters from the location at which it last accessed the

database. A Mode II device that has been in a powered state shall re-check its location and access the database every 20 minutes to verify that the operating channel(s) continue to be available. Mode II devices must adjust their use of channels in accordance with channel availability schedule information provided by their database for the 60 minute period beginning at the time of the device last accessed the database for a list of available channels. A Mode II device may load channel availability information for multiple locations around, *i.e.,* in the vicinity of, its current location and use that information in its operation. A Mode II device may use such available channel information to define a geographic area within which it can operate on the same available channels at all locations, for example a Mode II device could calculate a bounded area in which a channel or channels are available at all locations within the area and operate on a mobile basis within that area. A Mode II device using such channel availability information for multiple locations must contact the database again if/when it moves beyond the boundary of the area where the channel availability data is valid, and must access the database once every 20 minutes even if it has not moved beyond that range to verify that the operating channel(s) continue to be available. Operation must cease immediately if the database indicates that the channel is no longer available.

* * * * *

(v) Device manufacturers and database administrators may implement a system that pushes updated channel availability information from the database to white space devices. However, the use of such systems is not mandatory, and the requirements for white space devices to validate the operating channel at least once every 20 minutes continue to apply if such a system is used.

* * * * *

■ 10. Section 15.712 is amended by revising paragraphs (a), (f), and (h), and by adding paragraphs (i) and (j) to read as follows:

§ 15.712 Interference protection requirements.

(a) Digital television stations, and digital and analog Class A TV, low power TV, TV translator and TV booster stations:

(1) *Protected contour.* White space devices must protect digital and analog TV services within the contours shown in the following table. These contours are calculated using the methodology in § 73.684 of this chapter and the R–6602 curves contained in § 73.699 of this chapter.

Type of station	Protected contour		
	Channel	Contour (dBu)	Propagation curve
Analog: Class A TV, LPTV, translator and booster	Low VHF (2–6)	47	F(50,50)
	High VHF (7–13)	56	F(50,50)
	UHF (14–69)	64	F(50,50)
Digital: Full service TV, Class A TV, LPTV, translator and booster	Low VHF (2–6)	28	F(50,90)
	High VHF (7–13)	36	F(50,90)
	UHF (14–51)	41	F(50,90)

(2) *Required separation distance.* White space devices must be located outside the contours indicated in paragraph (a)(1) of this section of co-channel and adjacent channel stations by at least the minimum distances specified in the following tables. If a device operates between two defined power levels, it must comply with the separation distances for the higher power level. Fixed and personal/portable devices operating at an EIRP of 40 mW or less are not required to meet adjacent channel separation distances.

Antenna height above average terrain of unlicensed device	Required separation in kilometers from co-channel digital or analog TV (full service or low power) protected contour					
	16 dBm (40 mW)	20 dBm (100 mW)	24 dBm (250 mW)	28 dBm (625 mW)	32 dBm (1600 mW)	36 dBm (4 watts)
Personal/portable	1.3	1.7	N/A	N/A	N/A	N/A
Less than 3 meters	1.3	1.7	2.1	2.7	3.3	4.0
3–Less than 10 meters	2.4	3.1	3.8	4.8	6.1	7.3
10–Less than 30 meters	4.2	5.1	6.0	7.1	8.9	11.1
30–Less than 50 meters	5.4	6.5	7.7	9.2	11.5	14.3
50–Less than 75 meters	6.6	7.9	9.4	11.1	13.9	18.0
75–Less than 100 meters	7.7	9.2	10.9	12.8	17.2	21.1
100–Less than 150 meters	9.4	11.1	13.2	16.5	21.4	25.3
150–Less than 200 meters	10.9	12.7	15.8	19.5	24.7	28.5
200–250 meters	12.1	14.3	18.2	22.0	27.3	31.2

Antenna height above average terrain of unlicensed device	Required separation in kilometers from adjacent channel digital or analog TV (full service or low power) protected contour				
	20 dBm (100 mW)	24 dBm (250 mW)	28 dBm (625 mW)	32 dBm (1600 mW)	36 dBm (4 watts)
Personal/portable	0.1	N/A	N/A	N/A	N/A
Less than 3 meters	0.1	0.1	0.1	0.1	0.2
3–Less than 10 meters	0.1	0.2	0.2	0.2	0.3
10–Less than 30 meters	0.2	0.3	0.3	0.4	0.5
30–Less than 50 meters	0.3	0.3	0.4	0.5	0.7
50–Less than 75 meters	0.3	0.4	0.5	0.7	0.8

Antenna height above average terrain of unlicensed device	Required separation in kilometers from adjacent channel digital or analog TV (full service or low power) protected contour				
	20 dBm (100 mW)	24 dBm (250 mW)	28 dBm (625 mW)	32 dBm (1600 mW)	36 dBm (4 watts)
75–Less than 100 meters	0.4	0.5	0.6	0.8	1.0
100–Less than 150 meters	0.5	0.6	0.8	0.9	1.2
150–Less than 200 meters	0.5	0.7	0.9	1.1	1.4
200–250 meters	0.6	0.8	1.0	1.2	1.5

(3) The antenna height above ground for a fixed device may not exceed 30 meters.

* * * * *

(f) *Low power auxiliary services, including wireless microphones:* Fixed devices are not permitted to operate within 1 km, and personal/portable white space devices will not be permitted to operate within 400 meters, of the coordinates of registered low power auxiliary station sites on the registered channels during the designated times they are used by low power auxiliary stations.

* * * * *

(h) *Radio astronomy services:* (1) Operation of fixed and personal/portable devices is prohibited within 2.4 kilometers at the following locations.

(i) The Naval Radio Research Observatory in Sugar Grove, West Virginia at 38 30 58 N and 79 16 48 W.

(ii) The Table Mountain Radio Receiving Zone (TMRZ) at 40 08 02 N and 105 14 40 W.

(iii) The following facilities:

Observatory	Latitude (deg/min/sec)	Longitude (deg/min/sec)
Arecibo Observatory	18 20 37 N	066 45 11 W
Green Bank Telescope (GBT)	38 25 59 N	079 50 23 W
Very Long Baseline Array (VLBA) Stations:		
Pie Town, NM	34 18 04 N	108 07 09 W
Kitt Peak, AZ	31 57 23 N	111 36 45 W
Los Alamos, NM	35 46 30 N	106 14 44 W
Ft. Davis, TX	30 38 06 N	103 56 41 W
N. Liberty, IA	41 46 17 N	091 34 27 W
Brewster, WA	48 07 52 N	119 41 00 W
Owens Valley, CA	37 13 54 N	118 16 37 W
St. Croix, VI	17 45 24 N	064 35 03 W
Hancock, NH	42 56 01 N	071 59 12 W
Mauna Kea, HI	19 48 05 N	155 27 20 W

(2) White space devices may not operate on channel 37 within the quiet zone at Green Bank WV defined in § 1.924(a) of this chapter or within the quiet zone on the islands of Puerto Rico, Desecheo, Mona, Vieques or Culebra defined in § 1.924(d) of this chapter.

(i) *WMTS:* Devices operating on channel 37 must comply with the following co-channel and adjacent channel separation distances from WMTS receivers.

Antenna height above average terrain of unlicensed device	Required co-channel separation distances in kilometers from WMTS sites					
	16 dBm (40 mW)	20 dBm (100 mW)	24 dBm (250 mW)	28 dBm (625 mW)	32 dBm (1600 mW)	36 dBm (4 watts)
Less than 3 meters	0.3	0.4	0.5	0.6	0.8	1.0
3–Less than 10 meters	0.6	0.7	0.9	1.1	1.4	1.7
10–Less than 30 meters	1.0	1.2	1.5	1.9	2.7	2.9
30–Less than 50 meters	1.2	1.6	2.1	2.4	3.0	3.8
50–Less than 75 meters	1.5	1.9	2.4	2.9	3.6	4.5
75–Less than 100 meters	1.7	2.2	2.7	3.3	4.2	5.3
100–Less than 150 meters	2.1	2.7	3.1	3.8	5.0	6.5
150–Less than 200 meters	2.5	3.1	3.4	4.3	5.8	7.4
200–250 meters	2.8	3.5	3.7	4.7	6.3	8.0

Antenna height above average terrain of unlicensed device	Required adjacent channel separation distances in kilometers from WMTS sites					
	16 dBm (40 mW)	20 dBm (100 mW)	24 dBm (250 mW)	28 dBm (625 mW)	32 dBm (1600 mW)	36 dBm (4 watts)
Personal/portable	0.1	0.1	N/A	N/A	N/A	N/A
Less than 3 meters	0.1	0.1	0.1	0.1	0.1	0.1
3–Less than 10 meters	0.1	0.1	0.1	0.1	0.1	0.1
10–Less than 30 meters	0.1	0.1	0.1	0.1	0.2	0.2
30–Less than 50 meters	0.1	0.1	0.1	0.2	0.2	0.3
50–Less than 75 meters	0.1	0.1	0.2	0.2	0.3	0.3
75–Less than 100 meters	0.1	0.2	0.2	0.2	0.3	0.4

Antenna height above average terrain of unlicensed device	Required adjacent channel separation distances in kilometers from WMTS sites					
	16 dBm (40 mW)	20 dBm (100 mW)	24 dBm (250 mW)	28 dBm (625 mW)	32 dBm (1600 mW)	36 dBm (4 watts)
100–Less than 150 meters	0.2	0.2	0.2	0.3	0.4	0.5
150–Less than 200 meters	0.2	0.2	0.3	0.3	0.4	0.6
200–250 meters	0.2	0.2	0.3	0.4	0.5	0.6

(j) *Repurposed 600 MHz band:* Fixed and personal/portable devices operating in the repurposed 600 MHz Band must comply with the following co-channel and adjacent channel separation distances outside the defined polygonal area encompassing the base stations deployed by a part 27 600 MHz Band licensee that has commenced operation. For the purpose of this rule, co-channel means any frequency overlap between a channel used by a white space device and a five megahertz spectrum block used by a part 27 600 MHz Band licensee, and adjacent channel means a frequency separation of zero to four megahertz between the edge of a channel used by a white space device and the edge of a five megahertz spectrum block used by a part 27 600 MHz Band licensee.

(1) On frequencies used by wireless uplink services:

Antenna height above average terrain of unlicensed device	Required co-channel separation distances in kilometers between white space devices in the uplink band and 600 MHz Band base stations					
	16 dBm (40 mW)	20 dBm (100 mW)	24 dBm (250 mW)	28 dBm (625 mW)	32 dBm (1600 mW)	36 dBm (4 watts)
Less than 3 meters	5	6	7	9	12	15
3–Less than 10 meters	9	11	14	17	22	27
10–Less than 30 meters	15	19	24	30	38	47
30–Less than 50 meters	20	24	31	38	49	60
50–Less than 75 meters	24	30	37	47	60	60
75–Less than 100 meters	27	34	43	54	60	60
100–Less than 150 meters	33	42	53	60	60	60
150–Less than 200 meters	39	49	60	60	60	60
200–250 meters	43	54	60	60	60	60

Antenna height above average terrain of unlicensed device	Required adjacent channel separation distances in meters between white space devices in the uplink band and 600 MHz Band base stations					
	16 dBm (40 mW)	20 dBm (100 mW)	24 dBm (250 mW)	28 dBm (625 mW)	32 dBm (1600 mW)	36 dBm (4 watts)
Less than 3 meters	112	141	177	223	282	354
3–Less than 10 meters	204	257	323	407	514	646
10–Less than 30 meters	354	445	560	704	890	1120
30–Less than 50 meters	457	575	723	909	1150	1446
50–Less than 75 meters	560	704	885	1113	1408	1770
75–Less than 100 meters	646	813	1022	1285	1626	2044
100–Less than 150 meters	792	996	1252	1574	1991	2504
150–Less than 200 meters	914	1150	1446	1818	2299	2891
200–250 meters	1022	1285	1616	2033	2571	3232

(2) On frequencies used by wireless downlink services: 35 kilometers for co-channel operation, and 31 kilometers for adjacent channel operation.

■ 11. Section 15.713 is amended by:

■ a. Revising the section heading;

■ b. Adding paragraph (b)(2)(v); and

■ c. Revising paragraph (h)(4), removing and reserving paragraph (h)(9), revising paragraph (h)(10), and adding paragraph (h)(11).

The revisions and additions read as follows:

§ 15.713 White spaces database.

* * * * *

(b) * * *

(2) * * *

(v) WMTS operating locations.

* * * * *

(h) * * *

(4) PLMRS/CMRS base station operations located more than 80 km from the geographic centers of the 13 metropolitan areas defined in § 90.303(a) of this chapter (*e.g.,* in accordance with a waiver).

(i) Transmitter location (latitude and longitude in NAD 83) or geographic area of operations.

(ii) TV channel of operation.

(iii) Call sign.

* * * * *

(10) 600 MHz Band in areas where the part 27 600 MHz Band licensee has commenced operations.

(i) Area within a part 27 600 MHz Band licensee's PEA where it has commenced or will commence operations. This area must be delineated by at minimum of eight and a maximum of 120 geographic coordinates;

(ii) Identification of the frequencies on which the part 27 600 MHz Band wireless licensee has commenced operations;

(iii) Call sign.

(iv) Date of commencement of operations.

(11) WMTS operating locations obtained from the WMTS frequency coordination database established under § 95.1113(b)(2) of this chapter.

(i) Frequency of operation (*i.e.,* channel 37),

(ii) Geographic coordinates of transmitters, and

(iii) Cross reference to the registration in the WMTS frequency coordination database (*e.g.,* record number).

* * * * *

■ 12. Section 15.714 is amended by revising the section heading and paragraph (a) to read as follows:

§ 15.714 White spaces database administration fees.

(a) A white spaces database administrator may charge a fee for provision of lists of available channels to fixed and personal/portable devices and for registering fixed devices. This provision applies to devices that operate in the TV bands, the repurposed 600 MHz Band, the 600 MHz guard bands, including the duplex gap, and Channel 37. White spaces database administrators may also charge fees for providing lists of available channels to users of unlicensed wireless microphones.

* * * * *

■ 13. Section 15.715 is amended by revising the section heading and paragraph (l), and by adding paragraphs (n) and (o) to read as follows:

§ 15.715 White spaces database administrator.

* * * * *

(l) If more than one database is developed, the database administrators shall cooperate to develop a standardized process for providing the data collected for the facilities listed in § 15.713(b)(2) to all other white spaces databases within ten minutes to ensure consistency in the records of protected facilities.

* * * * *

(n) Establish a procedure for registering the locations, operating frequencies and starting dates for the areas where a part 27 600 MHz Band licensee has commenced operations.

(o) Establish a procedure for obtaining the locations where the WMTS is used from the WMTS coordination database established under § 95.1117(b)(2) of this chapter.

PART 74—EXPERIMENTAL RADIO, AUXILIARY, SPECIAL BROADCAST AND OTHER PROGRAM DISTRIBUTIONAL SERVICES

■ 14. The authority citation for part 74 continues to read as follows:

Authority: 47 U.S.C. 154, 302a, 303, 307, 309, 336 and 554.

■ 15. Section 74.801 is amended by adding the definitions for ''600 MHz duplex gap'' and ''Repurposed 600 MHz Band'' in alphabetical order to read as follows:

§ 74.801 Definitions.

600 MHz duplex gap. An 11 megahertz guard band that separates wireless uplink and downlink frequencies within the 600 MHz Band as determined by the outcome of the auction conducted pursuant to *Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions,* Report and Order, GN Docket No. 12–268 (FCC 14–50), 29 FCC 6567 (2014).

Repurposed 600 MHz Band. Frequencies that will be reallocated and reassigned for part 27 600 MHz Band services as determined by the outcome of the auction conducted pursuant to *Expanding the Economic and Innovation Opportunities of Spectrum Through Incentive Auctions, Report and Order,* GN Docket No. 12–268 (FCC 14–50), 29 FCC 6567 (2014).

■ 16. Section 74.802 is amended by revising paragraphs (a) and paragraph (c) introductory text to read as follows:

§ 74.802 Frequency assignment.

(a) Frequencies within the following bands may be assigned for use by low power auxiliary stations:

26.100–26.480 MHz
54.000–72.000 MHz
76.000–88.000 MHz
161.625–161.775 MHz (except in Puerto Rico or the Virgin Islands)
174.000–216.000 MHz
450.000–451.000 MHz
455.000–456.000 MHz
470.000–488.000 MHz
488.000–494.000 MHz (except Hawaii)
494.000–608.000 MHz
614.000–698.000 MHz
944.000–952.000 MHz

The four megahertz segment from one to five megahertz above the lower edge of the 600 MHz duplex gap.

* * * * *

(c) Specific frequency operation is required when operating within the 600 MHz duplex gap or the bands allocated for TV broadcasting.

* * * * *

■ 17. Section 74.861 is amended by revising paragraph (e) introductory text and adding paragraph (e)(1)(iii) to read as follows:

§ 74.861 Technical requirements.

* * * * *

(e) For low power auxiliary stations operating in the 600 MHz duplex gap and the bands allocated for TV broadcasting, the following technical requirements apply:

(1) * * *

(iii) 600 MHz duplex gap—20 mW.

* * * * *

[FR Doc. 2014–26674 Filed 11–20–14; 8:45 am]

BILLING CODE 6712–01–P

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Part V

The President

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Title 3—

The President

Memorandum of September 26, 2014

Certification Concerning U.S. Participation in the United Nations Multidimensional Integrated Stabilization Mission in the Central African Republic Consistent With Section 2005 of the American Servicemembers' Protection Act

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States of America, and consistent with section 2005 of the American Servicemembers' Protection Act of 2002 (22 U.S.C. 7424), concerning the participation of members of the Armed Forces of the United States in certain United Nations peacekeeping and peace enforcement operations, I hereby certify that members of the U.S. Armed Forces participating in the United Nations Multidimensional Integrated Stabilization Mission in the Central African Republic are without risk of criminal prosecution or other assertion of jurisdiction by the International Criminal Court (ICC) because the Central African Republic has entered into an agreement in accordance with Article 98 of the Rome Statute preventing the ICC from proceeding against members of the Armed Forces of the United States present in that country.

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

THE WHITE HOUSE,
Washington, September 26, 2014

[FR Doc. 2014–27847
Filed 11–20–14; 11:15 am]
Billing code 4710–10

Presidential Documents

Memorandum of September 30, 2014

Delegation of Authority Under Section 614 of the Foreign Assistance Act of 1961

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, I hereby delegate to the Secretary of State the authority under section 614 of the Foreign Assistance Act of 1961 (FAA) to determine whether it is important to the security interests of the United States to furnish up to $123,000,000 in funds made available pursuant to chapter 8 of part I of the FAA to provide assistance for Ukraine, Tunisia, Honduras, El Salvador, Guatemala, Costa Rica, Panama, Nigeria, Albania, and Vietnam without regard to any provision of law within the scope of section 614(a)(1) of the FAA and to authorize the furnishing of such assistance.

You are authorized and directed to publish this memorandum in the *Federal Register*.

THE WHITE HOUSE,
Washington, September 30, 2014

[FR Doc. 2014–27856
Filed 11–20–14; 11:15 am]
Billing code 4710–10

Presidential Documents

Presidential Determination No. 2014–17 of September 30, 2014

Presidential Determination on Refugee Admissions for Fiscal Year 2015

Memorandum for the Secretary of State

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

The admission of up to 70,000 refugees to the United States during Fiscal Year (FY) 2015 is justified by humanitarian concerns or is otherwise in the national interest; provided that this number shall be understood as including persons admitted to the United States during FY 2015 with Federal refugee resettlement assistance under the Amerasian immigrant admissions program, as provided below.

The admissions numbers shall be allocated among refugees of special humanitarian concern to the United States in accordance with the following regional allocations; provided that the number of admissions allocated to the East Asia region shall include persons admitted to the United States during FY 2015 with Federal refugee resettlement assistance under section 584 of the Foreign Operations, Export Financing, and Related Programs Appropriations Act of 1988, as contained in section 101(e) of Public Law 100–202 (Amerasian immigrants and their family members):

Africa	17,000
East Asia	13,000
Europe and Central Asia	1,000
Latin America and Caribbean	4,000
Near East and South Asia	33,000
Unallocated Reserve	2,000

The 2,000 unallocated refugee numbers shall be allocated to regional ceilings, as needed. Upon providing notification to the Judiciary Committees of the Congress, you are hereby authorized to use unallocated admissions in regions where the need for additional admissions arises.

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

Consistent with section 101(a)(42) of the Act (8 U.S.C. 1101(a)(42)), and after appropriate consultation with the Congress, I also specify that, for FY 2015, the following persons may, if otherwise qualified, be considered refugees for the purpose of admission to the United States within their countries of nationality or habitual residence:

a. Persons in Cuba

b. Persons in Eurasia and the Baltics

c. Persons in Iraq

d. Persons in Honduras, Guatemala, and El Salvador

e. In exceptional circumstances, persons identified by a United States Embassy in any location

You are authorized and directed to publish this determination in the *Federal Register*.

THE WHITE HOUSE,
Washington, September 30, 2014

[FR Doc. 2014–27860
Filed 11–20–14; 11:15 am]
Billing code 4710–10

Presidential Documents

Presidential Determination No. 2014–18 of September 30, 2014

Determination With Respect to the Child Soldiers Prevention Act of 2008

Memorandum for the Secretary of State

Pursuant to section 404 of the Child Soldiers Prevention Act of 2008 (CSPA) (title IV, Public Law 110–457), as amended, I hereby determine that it is in the national interest of the United States: to waive the application of the prohibition in section 404(a) of the CSPA with respect to Rwanda, Somalia, and Yemen; to waive in part the application of the prohibition in section 404(a) of the CSPA with respect to the Central African Republic to allow for provision of International Military Education and Training (IMET); to waive in part the application of the prohibition in section 404(a) of the CSPA with respect to the Democratic Republic of the Congo to allow for provision of IMET, nonlethal Excess Defense Articles, the issuance of licenses for direct commercial sales of U.S. origin nonlethal defense articles, Peacekeeping Operations (PKO) assistance, and support provided pursuant to section 1208 of the National Defense Authorization Act for Fiscal Year 2014 to the extent such support would be restricted by the CSPA; and to waive in part the application of the prohibition in section 404(a) of the CSPA with respect to South Sudan to allow for the provision of PKO assistance and support provided pursuant to section 1208 of the National Defense Authorization Act for Fiscal Year 2014 to the extent such support would be restricted by the CSPA. I hereby waive such provisions accordingly.

You are authorized and directed to submit this determination to the Congress, along with the accompanying Memorandum of Justification, and to publish the determination in the *Federal Register*.

THE WHITE HOUSE,
Washington, September 30, 2014

[FR Doc. 2014–27870
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