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

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## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 73

[NRC–2015–0179]

RIN 3150–AJ64

### Cyber Security at Fuel Cycle Facilities

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Final regulatory basis; availability.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is making available a final regulatory basis document to support a rulemaking that would amend its regulations by adopting new cyber security requirements for certain nuclear fuel cycle facility (FCF) licensees in order to address safety, security, and safeguards consequences of concern. The NRC is not seeking public comments on this document. There will be an opportunity for formal public comment on the proposed rule when it is published in the **Federal Register**.

**DATES:** The final regulatory basis is publicly available April 12, 2016.

**ADDRESSES:** Please refer to Docket ID NRC–2015–0179 when contacting the NRC about the availability of information for this document. You may obtain publicly-available information related to this document by any of the following methods:

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC–2015–0179. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov). For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

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- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

**FOR FURTHER INFORMATION CONTACT:** Matthew Bartlett, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–7154; email [Matthew.Bartlett@nrc.gov](mailto:Matthew.Bartlett@nrc.gov).

#### SUPPLEMENTARY INFORMATION:

#### I. Background

In a September 4, 2015, **Federal Register** document (80 FR 53478), the NRC solicited comment from members of the public on a draft regulatory basis addressing the need for a rulemaking to implement cyber security for FCFs. The public comment period ended on October 5, 2015. The NRC received a total of 9 comment submissions from nongovernment organizations and industry. The NRC staff reviewed and considered the comments in finalizing the regulatory basis. The final regulatory basis is available in ADAMS under Accession No. ML15355A466 or on the Federal rulemaking Web site, [www.regulations.gov](http://www.regulations.gov), under Docket ID NRC–2015–0179.

#### II. Publicly-Available Documents

As the NRC continues its ongoing proposed rulemaking effort to implement cyber security requirements for FCFs in part 73 of title 10 of the *Code of Federal Regulations*, the NRC is making documents publicly available on the Federal rulemaking Web site, [www.regulations.gov](http://www.regulations.gov), under Docket ID NRC–2015–0179. By making these documents publicly available, the NRC seeks to inform stakeholders of the current status of the NRC's rulemaking development activities and to provide preparatory material for future public meetings.

The NRC may post additional materials relevant to this rulemaking at [www.regulations.gov](http://www.regulations.gov), under Docket ID NRC–2015–0179. Please take the following actions if you wish to receive alerts when changes or additions occur in a docket folder: (1) Navigate to the docket folder (NRC–2015–0179); (2) click the “Email Alert” link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

#### III. Plain Writing

The Plain Writing Act of 2010, (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, well-organized manner that also follows other best practices appropriate to the subject or field and the intended audience. Although regulations are exempt under the Act, the NRC is applying the same principles to its rulemaking documents. Therefore, the NRC has written this document to be consistent with the Plain Writing Act.

Dated at Rockville, Maryland, this 1st day of April, 2016.

For the Nuclear Regulatory Commission.

**Shana R. Helton,**

*Acting Deputy Director, Division of Fuel Cycle Safety, Safeguards, and Environmental Review, Office of Nuclear Material Safety and Safeguards.*

[FR Doc. 2016–08324 Filed 4–11–16; 8:45 am]

**BILLING CODE 7590–01–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Parts 61 and 141

[Docket No.: FAA–2015–1846; Amdt. Nos. 61–136, 141–18]

RIN 2120–AK71

#### Aviation Training Device Credit for Pilot Certification

**AGENCY:** Federal Aviation Administration (FAA), Department of Transportation (DOT).

**ACTION:** Final rule.

**SUMMARY:** This rulemaking relieves burdens on pilots seeking to obtain aeronautical experience, training, and certification by increasing the allowed use of aviation training devices. These actions are necessary to bring the regulations in line with the current



capabilities of aviation training devices and the needs and activities of the general aviation training community and pilots.

**DATES:** This rule is effective May 12, 2016.

**ADDRESSES:** For information on where to obtain copies of rulemaking documents and other information related to this final rule, see “How To Obtain Additional Information” in the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** Marcel Bernard, Airmen Certification and Training Branch, Flight Standards Service, AFS-810, Federal Aviation Administration, 898 Airport Park Road, Suite 204, Glen Burnie, MD 21061; telephone: (410) 590-5364 x235 email [marcel.bernard@faa.gov](mailto:marcel.bernard@faa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Executive Summary**

This rule finalizes the notice of proposed rulemaking (NPRM) regarding the use of aviation training devices for pilot certification. 80 FR 34338 (Jun. 16, 2015). The NPRM proposed to increase the maximum time that may be credited in an aviation training device (ATD) toward the aeronautical experience requirements for an instrument rating under § 61.65(i). The NPRM proposed to permit a person to credit a maximum of 20 hours of aeronautical experience acquired in an approved ATD toward the requirements for an instrument rating. By letter of authorization (LOA), devices that qualify as advanced aviation training devices (AATDs) were proposed to be authorized for up to 20 hours of experience to meet the instrument time requirements. Devices that qualify as basic aviation training devices (BATDs) were proposed to be authorized, by LOA, for a maximum of 10 hours of experience to meet the instrument time requirements.

Based on the comments received to the NPRM, the FAA is revising § 61.65 to include a specified allowance of 10 hours for BATDs and 20 hours for AATDs in part 61 (combined use not to exceed 20 hours) for the instrument rating.

The NPRM also addressed the use of ATDs in approved instrument rating courses. The NPRM proposed to amend appendix C to part 141 to increase the limit on the amount of training hours that may be accomplished in an ATD in an approved course for an instrument rating. The FAA proposed to allow ATDs to be used for no more than 40% of the total flight training hour requirements in an approved instrument rating course.

Based on the comments received to the NPRM, the FAA is revising appendix C to part 141 to include a specified allowance of 25% of creditable time in BATDs<sup>1</sup> and 40% of creditable time for AATDs under part 141 (not to exceed 40% total time) for the instrument rating.

Currently, § 61.65(i) requires a pilot who is logging instrument time in an ATD to wear a view-limiting device. The NPRM proposed to revise § 61.65(i)(4) to eliminate the requirement that pilots accomplishing instrument time in an ATD wear a view-limiting device. The FAA is finalizing this proposal without change.

**II. Authority for This Rulemaking**

The FAA's authority to issue rules on aviation safety is found in Title 49 of the United States Code (49 U.S.C.). Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in 49 U.S.C. 106(f), which establishes the authority of the Administrator to promulgate regulations and rules; 49 U.S.C. 44701(a)(5), which requires the Administrator to promote safe flight of civil aircraft in air commerce by prescribing regulations and setting minimum standards for other practices, methods, and procedures necessary for safety in air commerce and national security; and 49 U.S.C. 44703(a), which requires the Administrator to prescribe regulations for the issuance of airman certificates when the Administrator finds, after investigation, that an individual is qualified for, and physically able to perform the duties related to, the position authorized by the certificate.

**III. Background**

Since the 1970s, the FAA has gradually expanded the permitted use of flight simulation for training—first permitting simulation to be used in air carrier training programs and eventually permitting pilots to credit time in devices toward the aeronautical experience requirements for airman certification and recency. Currently, title 14 of the Code of Federal Regulations (14 CFR) part 60 governs the qualification of flight simulation training devices (FSTDs), which include

full flight simulators (FFSs) level A through D and flight training devices (FTDs) levels 4 through 7. The FAA has, however, approved other devices, including ATDs, for use in pilot certification training, under the authority provided in 14 CFR 61.4(c).<sup>2</sup>

For over 30 years, the FAA has issued LOAs to manufacturers of ground trainers, personal computer-based aviation training devices (PCATD), FTDs (levels 1 through 3), BATDs, and AATDs. These LOAs were based on guidance provided in advisory circulars (ACs) that set forth the qualifications and capabilities for the devices. Prior to 2008, most LOAs were issued under the guidance provided in AC 61-126, Qualification and Approval of Personal Computer-Based Aviation Training Devices, and AC 120-45, Airplane Flight Training Device Qualification. Starting in July 2008, the FAA approved devices in accordance with AC 61-136, FAA Approval of Basic Aviation Training Devices (BATD) and Advanced Aviation Training Devices (AATD). More recently, on December 3, 2014, the FAA published a revision to AC 61-136A, Approval of Aviation Training Devices and Their Use for Training and Experience.

In 2009, the FAA issued a final rule that for the first time introduced the term “aviation training device” into the regulations and placed express limits on the amount of instrument time in an ATD that could be credited toward the aeronautical experience requirements for an instrument rating.<sup>3</sup>

Since the 2009 final rule, § 61.65(i) has provided that no more than 10 hours of instrument time received in an ATD may be credited toward the instrument time requirements of that section. In addition, appendix C to part 141 permits an ATD to be used for no more than 10% of the total flight training hour requirements of an approved course for an instrument rating.

Prior to the 2009 final rule, the FAA had issued hundreds of LOAs to

<sup>2</sup> Section 61.4(c) states that the “Administrator may approve a device other than a flight simulator or flight training device for specific purposes.”

<sup>3</sup> In a 2007 NPRM, the FAA proposed to limit the time in a personal computer-based aviation training device that could be credited toward the instrument rating. *Pilot, Flight Instructor, and Pilot School Certification* NPRM, 72 FR 5806 (Feb. 7, 2007). Three commenters recommended that the FAA use the terms “basic aviation training device” (BATD) and “advanced aviation training device” (AATD). *Pilot, Flight Instructor, and Pilot School Certification* Final Rule, 74 FR 42500 (Aug. 21, 2009) (“2009 Final Rule”). In response to the commenters, the FAA changed the regulatory text in the final rule to “aviation training device,” noting BATDs and AATDs “as being aviation training devices (ATD) are defined” in an advisory circular.

<sup>1</sup> If a course of training is approved under the minimum requirements as prescribed in part 141, appendix C, for the instrument rating (35 hours of training required), 25% in a BATD would equate to 8.75 hours and 40% in an AATD would equate to 14 hours.

manufacturers of devices that permitted some ATDs (as well as ground trainers, and FTDs (levels 1 through 3)) to be used to a greater extent than was ultimately set forth in the regulations. The FAA continued to issue LOAs for AATDs in excess of the express limitations in the regulations after the publication of the 2009 final rule.

On January 2, 2014, the FAA published a notice of policy requiring manufacturers of ATDs to obtain new LOAs reflecting the appropriate regulatory allowances for ATD use. 79 FR 20.<sup>4</sup> The notice of policy stated the FAA's conclusion that it could not use LOAs to exceed express limitations that had been placed in the regulations through notice and comment rulemaking. The FAA noted that, since August 2013, LOAs issued for new devices reflect current regulatory requirements. However, manufacturers and operators who held LOAs issued prior to August 2013 acted in reliance on FAA statements that were inconsistent with the regulations. Therefore, the FAA granted a limited exemption from the requirement in the regulations to provide manufacturers, operators, and pilots currently training for an instrument rating time to adjust to the reduction in creditable hours. This short-term exemption was intended to provide an interim period to transition the LOAs for all previously approved devices in accordance with the new policy. The FAA found the exemption to be in the public interest in order to prevent undue harm caused by reasonable reliance on the LOAs.

As stated in the notice of policy, this short term exemption expired on January 1, 2015. The FAA explained that after that date, no applicant training for an instrument rating under part 61 may use more than 10 hours of instrument time in an ATD toward the minimum aeronautical experience requirements required to take the practical test for an instrument rating.<sup>5</sup> In addition, no instrument rating course approved under appendix C to part 141 may credit more than 10% of training in ATDs toward the total flight training hour requirements of the course (unless that program has been approved in accordance with § 141.55(d) or (e)).<sup>6</sup>

<sup>4</sup> "Notice of Policy Change for the Use of FAA Approved Training Devices," January 2, 2014.

<sup>5</sup> Under § 61.65, a person who applies for an instrument rating must have completed 40 hours of actual or simulated instrument time of which 15 hours must have been with an authorized instructor who holds the appropriate instrument rating.

<sup>6</sup> Under appendix C, each approved course for an instrument rating must include 35 hours of instrument training for an initial instrument rating or 15 hours of instrument training for an additional instrument rating.

To address the discrepancy between the level of ATD credit allowed historically by LOA and the lower allowances placed in the regulations, the FAA published a direct final rule that would have amended the regulations governing the use of ATDs.<sup>7</sup> The direct final rule would have increased the use of these devices for instrument training requirements above the levels established in the 2009 final rule. In developing this direct final rule, the FAA noted that ATD development has advanced to an impressive level of capability. Many ATDs can simulate weather conditions with variable winds, variable ceilings and visibility, icing, turbulence, high definition (HD) visuals, hundreds of different equipment failure scenarios, navigation specific to current charts and topography, specific navigation and communication equipment use, variable "aircraft specific" performance, and more. The visual and motion component of some of these devices permit maneuvers that require outside visual references in an aircraft to be successfully taught in an AATD. Many of these simulation capabilities were not possible in previously approved devices (such as PCATDs).

In the direct final rule, the FAA stated its belief that permitting pilots to log increased time in ATDs would encourage pilots to practice maneuvers until they are performed to an acceptable level of proficiency. In an ATD, a pilot can replay the training scenario, identify any improper action, practice abnormal/emergency procedures, and determine corrective actions without undue hazard or risk to persons or property. In this fashion, a pilot can continue to practice tasks and maneuvers in a safe, effective, and cost efficient means of maintaining proficiency.

#### IV. The Direct Final Rule

As described in the previous section, to address the discrepancy between FAA regulations and prior policy, on December 3, 2014, the FAA published a direct final rule that would have increased the allowed use of ATDs. The FAA received 20 comments to the direct final rule.<sup>8</sup>

*Credit for aeronautical experience requirements for an instrument rating:* The direct final rule would have increased the maximum time that may be credited in an ATD toward the aeronautical experience requirements

for an instrument rating under § 61.65(i). The direct final rule would have permitted a person to credit a maximum of 20 hours of aeronautical experience acquired in an approved ATD toward the requirements for an instrument rating. Devices that qualify as AATDs would have been authorized for up to 20 hours of experience to meet the instrument time requirements. Devices that qualify as BATDs would have been authorized for a maximum of 10 hours of experience to meet the instrument time requirements.

*Approved instrument rating courses:* The direct final rule also would have amended appendix C to part 141 to increase the limit on the amount of training hours that may be accomplished in an ATD in an approved course for an instrument rating. An ATD would have been permitted to be used for no more than 40% of the total flight training hour requirements in an approved instrument rating course.

*Comments received:* The FAA received 20 comments regarding these provisions. Eighteen comments supported the provisions. However, two commenters raised concerns. As those comments were adverse to the direct final rule, the FAA was required to withdraw the direct final rule, 80 FR 2001, (Jan. 15, 2015). 14 CFR 11.13. The comments received to the direct final rule and FAA's responses were discussed in the notice of proposed rulemaking published June 16, 2015. 80 FR 34338.

*View-limiting devices:* Under § 61.51(g), a person may log instrument time only for that flight time when the person operates an aircraft solely by reference to the instruments under actual or simulated conditions. When instrument time is logged in an aircraft, a pilot wears a view-limiting device to simulate instrument conditions and ensure that he or she is flying without utilizing outside visual references. Currently, § 61.65(i) requires a pilot who is logging instrument time in an ATD to wear a view-limiting device. The direct final rule would have revised § 61.65(i)(4) to eliminate the requirement that pilots accomplishing instrument time in an ATD wear a view-limiting device.

The purpose of a view-limiting device is to prevent a pilot (while training in an aircraft during flight) from having outside visual references that would naturally be present otherwise. These references are not available in a training device and a pilot has no opportunity to look outside for any useful visual references pertaining to the simulation. The FAA recognizes that the majority of these devices have a simulated visual

<sup>7</sup> 79 FR 71634, Dec. 3, 2014, withdrawn at 80 FR 2001, Jan. 15, 2015 (RIN 2120-AK62).

<sup>8</sup> The direct final rule and the comments received thereto may be found in FAA Docket No. FAA-2014-0987 at <http://www.regulations.gov>.

display that can be configured to be unavailable or represent “limited visibility” conditions that preclude any need for a view-limiting device to be worn by the student. This lack of visual references requires the pilot to give his or her full attention to the flight instruments which is the goal of any instrument training or experience. The FAA believes that using a training device can be useful because it trains the pilot to focus on, appropriately scan and interpret the flight instruments. Since these devices incorporate a visual system that can be configured to the desired visibility level, use of a view-limiting device would have no longer been required by the direct final rule.

When the FAA introduced § 61.65(i)(4) requiring view-limiting devices in the 2009 final rule, the preamble was silent as to why a view-limiting device was necessary. 74 FR 42500, 42523. Based on comments from industry, the FAA has determined that due to the sophistication of the flight visual representation for ATDs and the capability of presenting various weather conditions appropriate to the training scenario, a view-limiting device is unnecessary. Because persons operating an ATD can simulate both instrument and visual conditions, FAA LOAs specifically reference § 61.51 that stipulates a pilot can log instrument time only when operating the aircraft solely by reference to the instruments in actual or simulated instrument flight conditions.<sup>9</sup>

*Comments received:* The FAA received one comment in response to this provision in the direct final rule. The comment received to the direct final rule and FAA’s response were discussed in the notice of proposed rulemaking published June 16, 2015. 80 FR 34338.

## V. The Proposed Rule

After consideration of the comments received to the direct final rule, on June 16, 2015, the FAA published a notice of proposed rulemaking (80 FR 34338) proposing the following changes to 14 CFR parts 61 and 141. These changes were the same as in the direct final rule, 79 FR 71634, (Dec. 3, 2014), withdrawn at 80 FR 2001, (Jan. 15, 2015).

The FAA received a total of 60 comments to the notice of proposed rulemaking, 50 from individuals; five from flight schools; three from organizations representing pilots and flight instructors, including the Society of Aviation and Flight Educators

(SAFE), the Aircraft Owners and Pilots Association (AOPA), and the National Association of Flight Instructors (NAFI); one from an anonymous commenter purporting to represent Garmin International; and one from ATD manufacturer Redbird Flight Simulations. The proposed provisions, the comments received, and FAA’s responses are discussed in the following sections.

### A. Credit for the Aeronautical Experience Requirements for an Instrument Rating and Approved Instrument Rating Courses

The FAA proposed to increase the maximum time that may be credited in an ATD toward the instrument time requirements for an instrument rating under § 61.65(i). A person would be permitted to credit a maximum of 20 hours of instrument time in an approved ATD toward the requirements for an instrument rating.<sup>10</sup> Devices that qualify as AATDs would be authorized for up to 20 hours of instrument time. Devices that qualify as BATDs would be authorized for a maximum of 10 hours of instrument time. In light of this difference, pilots must—as required by current regulations—include in their logbooks the type and identification of any ATD that is used to accomplish aeronautical experience requirements for a certificate, rating, or recent flight experience. 14 CFR 61.51(b)(1)(iv). The FAA is retaining the existing limit of 20 hours of combined time in FFSs, FTDs, and ATDs that may be credited towards the aeronautical experience requirements for an instrument rating.

The FAA also proposed to amend appendix C to part 141 to increase the limit on the amount of training hours that may be accomplished in an ATD in an approved course for an instrument rating. An ATD could be used for no more than 40% of the total flight training hour requirements in an instrument rating course. The proposed rule did not change the current provisions in appendix C which limit credit for training in FFSs, FTDs, and ATDs, that if used in combination, cannot exceed 50% of the total flight training hour requirements of an instrument rating course.

In addition, the FAA proposed to amend § 141.41 to clarify the existing qualification and approval requirement for FSTDs and to add the qualification and approval of ATDs by the FAA,

which is currently conducted pursuant to § 61.4(c).

### 1. Comments Supporting the Proposed Provisions

The FAA received 57 comments in support of these proposed provisions, with 47 from individuals and 10 from organizations. Of the 57 comments received in support of the proposed rule, five recommended changes to the proposed regulations.

Nineteen individual commenters provided general support for the proposed rule. Nine commenters who identified themselves as pilots who had used ATDs for their own training provided support for the rule. They emphasized the value of being able to have a flight instructor pause the training, discuss the scenario, provide instant feedback and additional instruction, and then continue the training session. These individuals also believed that their training was enhanced by the ability to focus on the specific training tasks and ensure accurate, appropriate learning of the lesson. Commenters also noted that in an ATD instructors can focus solely on teaching rather than dividing their focus between teaching important instrument skills and general aircraft operations.

Commenters also emphasized the value of being presented with training scenarios that cannot be accomplished safely in the aircraft. Commenters cited emergency procedures, flight into thunderstorms, icing, and turbulent conditions as primary examples of conditions that can be simulated safely in ATDs.

SAFE, NAFI, and Redbird Flight Simulations also noted the ability of current ATDs to simulate a variety of aircraft types and configurations, as well as to simulate various conditions inside and outside the aircraft.

A number of individual commenters also noted the value, both financial and time saving, of accomplishing more repetitions in the same amount of time when using an ATD as opposed to using an aircraft. Two individual commenters estimated that time in an approved simulator with an instructor costs about \$100 per hour, while dual time in an instrument flight rules-certified aircraft is \$200 per hour or more. These commenters asserted that adding an extra 10 hours of simulator time cuts \$1,000 from the overall training cost. NAFI also noted that because the training is independent of weather and air traffic control conditions, a training syllabus can be followed more closely with use of the ATDs and the student can avoid unplanned, non-productive

<sup>9</sup> AC 61–136A Appendix 4, Training Content and Logging Provisions references limitations for logging instrument time.

<sup>10</sup> As required under § 61.51(g)(4), to log instrument time in an ATD for the purpose of a certificate or rating, an authorized instructor must be present.

time delays when attempting to practice a procedure.

Thirteen commenters who identified themselves as flight instructors supported the rule. They echoed the sentiments of those commenters who identified themselves as pilots who had used ATDs for their own training. Commenters discussed the belief that ATDs save lives, reduce training time and cost, reduce atmospheric and noise pollution, and produce safer pilots. They particularly noted the ability to train scenarios that would not be trained using an aircraft—thunderstorms, icing, etc. They emphasized the value of scenario-based training, followed closely by training in an aircraft. These commenters noted the importance of being able to train students regarding emergency procedures using meaningful repetition, until the commenters confirm the student's mastery of those skills. AOPA supported this view, stating that simulator training for an instrument rating allows instructors to provide a safer, more effective training experience. Redbird Flight Simulations also supported this view, stating that the ATD is the ideal place to learn, ask questions and practice, and the aircraft is the place where the student demonstrates what he or she has learned and can focus on gaining real-world flying experience with the basic fundamental instrument skills already engrained.

A few commenters noted that students whom they had trained initially in ATDs found the experience so useful that they returned for recurrent training in those same ATDs. One commenter noted FAA's inferred endorsement of the use of AATDs in Instrument Practical Test Standard (FAA-S-8081-4E, Chg 5) by the inclusion of tasks for an instrument proficiency check which may be credited using an AATD.

Five commenters commenting on behalf of flight schools also concurred with these comments. These commenters discussed the ability for pilots to practice situations and procedures that would not "normally" be possible to accomplish safely in an aircraft, including various weather conditions and simulated instrument failures. Commenters focused on the unique training that ATDs allow instructors to provide. As two commenters noted,

Aircraft are not classrooms and as such they are poor environments for learning. The AATDs allow for students experiencing difficult learning situations the opportunity to repeat the lesson easily, safely and as frequently as needed. Importantly, the instructor is able to focus entirely on

teaching rather than splitting his/her attention on traffic, ATC instructions and safe aircraft operation.<sup>11</sup>

These commenters emphasized that ATDs are only one component of the training curriculum and process, and that all learning in an ATD would be accompanied by training in the aircraft. They also noted that ATDs and aircraft do not replace each other. NAFI agreed, pointing out that a significant portion of training would still be required in an aircraft under the proposed regulations.

Commenters, including SAFE and several individuals, noted the use of simulators by other industries, including the United States military and air carriers. SAFE specifically cited a 1998 United States Air Force study regarding the transfer of training effectiveness.<sup>12</sup>

*FAA Response:* The FAA agrees with the commenters who support increased training time allowances in ATDs, including the statements discussing the increased dynamic training capability of these devices, cost savings, time savings, effective use of scenario-based training, and recent technical advancements that enhance the capabilities of ATDs. With over 30 years of experience evaluating, approving, and providing oversight for FSTDs and over 10 years approving ATDs, the FAA recognizes their evolving capabilities, safety benefits, and improved design justifying their increased use and credit for minimum pilot experience requirements.

One commenter noted the safety benefit of ATDs related to decommissioning of very high frequency omni-directional radio range (VORs), non-directional beacons (NDBs), the scarcity of localizer back-courses, and scarcity of outer markers. The commenter noted that the practical test standards still require the demonstration of a VOR approach for an instrument candidate. As the commenter explained:

Thus, instrument instructors must use a more limited set of VORs to conduct VOR instrument approach training, resulting in greater congestion around VORs during training maneuvers. Numerous FAA publications suggest avoiding concentrations around VORS, such as FAA-P-8740-51, 'How to Avoid a Midair Collision.' When one considers finding VOR approaches located on the airport (without a final approach fix) and those conducted off airport (those with a

final approach fix), the amount of time an instructor must spend exposed to the risk of a midair collision is quite large. The risk of a midair collision is non-existent in an ATD.<sup>13</sup>

*FAA Response:* The FAA agrees with the commenter that ATDs provide for unlimited choices when practicing electronic navigation, including instrument approaches, and the safety advantages afforded in these training devices. Traffic conflicts and geographic location are not a limitation when training in an FSTD or ATD. ATDs come with a database affording significant navigational choices. Advantages include executing navigation or instrument approach procedures to an airport that a pilot may not have experienced or executed in flight before.

## 2. Comments Providing Institutional Research Related to the Notice of Proposed Rulemaking

In the NPRM, the FAA specifically sought ". . . comment regarding any additional relevant data or institutional research that supports the training and safety advantages when using ATDs, or establishes that such devices do not enhance pilot training and flight safety."<sup>14</sup>

The FAA received two comments that specifically addressed this request.

One individual commenter cited an unpublished dissertation<sup>15</sup> that the commenter believed supported the use of ATDs. The commenter stated:

In her dissertation study, Kearns compared simulators far less capable than [sic] ATDs to a guided mental practice experimental technique. Though her results did not specifically evaluate ATDs, Kearn [sic] demonstrated how ATD-level simulators (and guided mental practice) effectively train skills enhancing mental workload and situational awareness.<sup>16</sup>

*FAA Response:* The FAA obtained and reviewed the unpublished Kearns dissertation.

The study author described the study as follows:

The purpose of this investigation was to assess the feasibility of guided mental practice, as an instructional strategy, embedded within an asynchronous computer-based non-technical training program for pilots. Two asynchronous computer-based single pilot resource management (SRM) training programs were developed for the study, varying only in the

<sup>13</sup> Anonymous, Docket No. FAA-2015-1846-0035.

<sup>14</sup> 80 FR 34338 at 34342.

<sup>15</sup> Kearns, S. (2007). "The Effectiveness of Guided Mental Practice in a Computer-Based Single Pilot Resource Management (SRM) Training," Ph.D. Dissertation, Capella University).

<sup>16</sup> Anonymous, Docket No. FAA-2015-1846-0035.

<sup>11</sup> Stephen Cunningham, Docket No. FAA-2015-1846-0034. Anonymous, Docket No. FAA-2015-1846-0038.

<sup>12</sup> Carretta, Thomas R., and Dunlap, Ronald D. "Transfer of Training Effectiveness in Flight Simulation: 1986-1997." United States Air Force Research Laboratory, 1998. <http://www.dtic.mil/get-tr-doc/pdf?AD=ADA362818>.

method of active practice. One version incorporated hands-on practice and another utilized a form of mental practice, termed guided mental practice. The term guided mental practice was developed to describe the process of mental practice which is facilitated by a computer-based training program, such as through the presentation of a video of a flight simulator scenario.<sup>17</sup>

The study author defined guided mental practice as:

... practice that took place without any hands-on interaction yet was facilitated by a computer-based flight simulator scenario embedded within an asynchronous online SRM training program. Participants were asked to view a video of a flight simulator in a particular scenario and imagine themselves as the pilot of the flight. Guided mental practice differs from traditional mental practice, which is typically an entirely internal process, as an external medium guides the learner through the practice exercise.<sup>18</sup>

Three groups were formed in the study (a) SRM training with hands-on practice, (b) SRM training with mental practice, and (c) a control group that received no training. The study used a sample size of 12 participants per condition.<sup>19</sup> All three groups of participants completed a high-fidelity flight simulator evaluation in which metrics assessed their situation awareness and mental workload, the two constructs targeted in the SRM training program.

The study found that although no difference existed between the practice conditions, groups that completed training with either hands-on or mental practice demonstrated improved situation awareness over the group that did not receive any training as measured by the situation awareness global assessment technique (SAGAT). Significant findings were not found with either of the metrics meant to assess workload: The National Aeronautics and Space Administration's task load index (NASA-TLX), and secondary task (ST) metrics.<sup>20</sup>

While this study did not directly address whether ATDs or other simulators provide benefit by increasing learning of piloting skills, it does appear to indicate that deliberate practice is important to pilot training, and that any practice, whether in a simulator or watching a video of a simulation and imagining oneself as the pilot, is more beneficial than no use of simulation at all in advance of the skill evaluation. While the FAA believes that this study may provide useful information for its

area of interest, the study was not focused on the decision point the FAA was considering regarding whether to move forward with this regulatory change—that is, data or institutional research that supports the training and safety advantages when using ATDs, or establishes that such devices do not enhance pilot training and flight safety. Situational awareness is one of many elements to be considered in evaluating pilot training and safety. The study did not consider whether skill sets were better learned by use of either guided mental practice or hands-on use of a simulator as compared with training in an aircraft only.

SAFE asserted that research shows that when properly utilized as part of a comprehensive training program such training devices actually speed up the learning process by allowing students to bypass areas of successful understanding and to concentrate on areas where more understanding and practice is required.<sup>21</sup>

*FAA Response:* The abstract of the study cited by SAFE reads as follows:

The purpose of this report was to review recent studies regarding the effectiveness of flight simulators as augmentation for "hands-on" flying training. Simulation-based training has been proposed to reduce costs, extend aircraft life, maintain flying proficiency, and provide more effective training, especially in areas difficult to train in operational aircraft. A review of the literature from 1986 to 1997 identified 67 articles, conference papers, and technical reports regarding simulator flying training and transfer. Of these, only 13 were related directly to transfer of training from the simulator to the aircraft. Studies of simulator effectiveness for training landing skills constituted a majority of the transfer studies, although a few examined other flying skills such as radial bombing accuracy and instrument and flight control. Results indicate that simulators are useful for training landing skills, bombing accuracy, and instrument and flight control. Generally, as the number of simulated sorties increases, performance improves, but this gain levels off after approximately 25 missions. Further, several studies indicate that successful transfer may not require high-fidelity simulators or whole-task training, thus reducing simulator development costs.

Evaluation of this literature is difficult for many reasons. Typically, researchers fail to report sufficient detail regarding research methods, training characteristics, and simulator fidelity. In addition to these methodological concerns, there is a lack of true simulator-to-aircraft transfer studies involving complex pilot skills. This may be due to problems such as inadequate

simulator design, cost, and availability, and access to simulators in operational flying units. Future directions in simulator transfer of training are discussed.<sup>22</sup>

Their literature review found that numerous studies conducted between 1986 and 1997 indicated that simulators were found to be useful for training landing skills. As the number of simulated sorties increased, performance increased, but the performance gain appeared to level off after approximately 25 missions. Two other studies considered for the literature review suggest that simulators provide an effective means to train instrument procedures and flight control. The results suggest that in order to produce transfer to the aircraft it may be necessary to train only the critical components of the task rather than the whole task. Authors emphasized the limitations of the literature review, including a lack of information regarding the simulator fidelity characteristics, research methods, and training characteristics among other challenges.

While the FAA found this literature review to provide some limited support for the agency's position, the review did not provide significant support for this position. Given the lack of information regarding simulators used, the effectiveness of the skills transfer, and the age of the review itself, it is likely that the literature review cannot be used to directly support the FAA's position. The FAA notes that FSTD and ATD technology has evolved significantly since this literature review was written and for that reason alone it is possible that studies conducted today would show different conclusions regarding the effectiveness of skill transfer, as simulators at all levels are more realistic and have greater information from which to provide simulation than that which existed 20 years ago.

Nonetheless, the FAA agrees that the use of ground based training devices in advance of flight training in an aircraft speeds up the overall process of learning. The FAA believes that practice decreases the time required in an actual aircraft to reach a level of proficiency required to successfully complete a practical test for a pilot certificate or rating. The Air Force research paper referenced by SAFE supports this assertion, but does not directly address the current capabilities of ATDs.

The individual commenter also believed that allowing increased hours in ATDs would increase economic demand for ATDs, thereby increasing competition and resulting in lower ATD

<sup>17</sup> Kearns, at 80.

<sup>18</sup> Kearns, at 12.

<sup>19</sup> Kearns, at 63.

<sup>20</sup> Kearns, at 82–83.

<sup>21</sup> Carretta, Thomas R., and Dunlap, Ronald D. "Transfer of Training Effectiveness in Flight Simulation: 1986–1997." United States Air Force Research Laboratory, 1998. <http://www.dtic.mil/get-tr-doc/pdf?AD=ADA362818>.

<sup>22</sup> Ibid.

prices and increased ATD innovation. The commenter cited a textbook that he or she believed supported this position.<sup>23</sup> The commenter further asserted that this increased competition will increase the quality of ATDs. The commenter compared the current situation regarding the use of ATDs to digital chart maturation,<sup>24</sup> arguing that when regulation is applied inappropriately, innovation may be stifled. Thus, the commenter asserted, expanded use of ATDs has derivative benefits consistent with a long-term view of aviation and safety.

*FAA Response:* The FAA generally agrees that permitting the greater use of ATDs may increase the demand for ATDs. In turn, the increased demand for ATDs may result in more firms entering the market, increasing competition, and perhaps in more technical innovation in ATDs. The FAA, however, restricts the economic impact analysis to the initial impact, as each succeeding economic impact is more speculative.

As noted previously, the intent of the specific request for information was to seek any additional relevant data or institutional research that supports the training and safety advantages when using ATDs, or establishes that such devices do not enhance pilot training and flight safety. The intent of this regulation is not to foster development of ATDs. The FAA emphasizes that even without this regulation persons are permitted to use ATDs and FSTDs to gain further experience in addition to any time that may be expressly creditable when using ATDs or FSTDs under the regulations.

Finally, the commenter asserted that economic growth of ATDs will offer enhanced applications of ATDs by researchers and innovators, contributing to aviation safety.<sup>25</sup> The commenter argued that ATD maturation in operational training environments will enable such forward-thinking training frameworks.

*FAA Response:* The FAA agrees that it is likely that the purchase and use of ATDs will increase with the additional FAA allowances provided for minimum

pilot experience requirements. Additionally, the Tuccio research paper referenced by the commenter generally supports the use of simulation in aviation pilot training specific to heuristics<sup>26</sup> but does not speak directly to any particular simulator design or capability.

### 3. Comments Supporting the Proposed Provisions With Changes

The FAA received five comments supporting the proposed rule but recommending changes to the proposed regulations. One commenter noted that in the proposed rule the FAA differentiated between the number of hours that were proposed to be credited toward the aeronautical experience requirements in an AATD (20 hours) versus a BATD (10 hours). The commenter noted that these differences were not stipulated in the proposed text of 14 CFR 61.65(i) regarding credit for aeronautical experience for the instrument rating, and that no differentiation was made between AATDs and BATDs in part 141 regarding approved instrument rating courses—either in the preamble or the regulatory text.

*FAA Response:* The FAA agrees with the commenter and believes that providing explicit and separate regulatory allowances for BATDs and AATDs, as currently provided in the FAA LOAs, is appropriate. Specificity in the regulation will better inform individuals receiving instrument training as to the appropriate allowances for the different levels of ATDs. Therefore, in this final rule the FAA is revising § 61.65 and appendix C to part 141 to include a specified allowance of 10 hours for BATDs and 20 hours for AATDs in part 61 (combined use not to exceed 20 hours), and 25% of creditable time in BATDs and 40% of creditable time for AATDs under part 141 (not to exceed 40% total time) for the instrument rating.

Currently, under the conditions and limitations set forth in the LOAs, training providers must provide copies of LOAs to people who receive training in the device. By providing a copy of the LOA, pilots who receive training will know the amount of training that may be logged in the device for the purpose of meeting the aeronautical experience requirements for a certificate or rating.

<sup>26</sup> Heuristics Merriam-Webster definition: Involving or serving as an aid to learning, discovery, or problem-solving by experimental and especially trial-and-error methods <heuristic techniques> <a heuristic assumption>; also: Of or relating to exploratory problem-solving techniques that utilize self-educating techniques (as the evaluation of feedback) to improve performance <a heuristic computer program>.

The same commenter believed that there could be confusion regarding the amount of time that can be credited when using a BATD, and when using percentages of simulator, FTD, AATD and BATD time that can be used in combination. For example, the commenter asserted that under appendix C to part 141, section 4(b)(4) as proposed, providing 40% of the required training in a BATD and 10% in a simulator would satisfy the letter of the rule.

*FAA Response:* As discussed previously, the FAA agrees with the commenter and is providing for separate specific regulatory allowances for BATDs and AATDs and clarifying the total creditable percentages of time when using BATDs and AATDs in combination with other FAA approved training devices.

The same commenter believed that the FAA was being inconsistent in its treatment of time that could be credited when using a BATD in part 61 versus part 141. The commenter noted that the FAA had proposed that 10 hours of the 40 hours required could be obtained using a BATD under part 61 (25% of the hours needed), whereas the FAA had proposed that 10% of the hours could be credited in a BATD under part 141 (3.5 hours).<sup>27</sup> Based on the commenter's understanding of the FAA proposal, the commenter recommended that the total number of hours that could be credited when using a BATD under part 141 be increased to 20% of the total hours (7 hours of the 35 hours required).

*FAA Response:* The FAA agrees with the commenter and will provide a consistent allowance in the regulation for ATD credit when using a BATD or AATD under part 61 and part 141. To provide a consistent allowance under part 141 training requirements for the instrument rating, in this final rule the FAA is allowing up to a 25% credit (8.75 hours) when using a BATD for the minimum training time requirements.

One commenter noted that the FAA does not differentiate regarding the use of AATDs versus BATDs anywhere else in part 141. The commenter believed that by differentiating AATDs from BATDs, it would now be possible to allow credit for AATD use toward flight times for private pilot, commercial pilot, flight instructor and additional rating courses. Another commenter requested that the FAA consider expanding the utilization of these devices for the private pilot rating as well from the current 2.5 hours to 10 hours. Another

<sup>27</sup> The 3.5 hours reflects 10% of the 35 hours of instrument training that is the minimum curriculum hours under appendix C to part 141.

<sup>23</sup> Vasigh, B., Fleming, K., Tacker, T. (2008) Introduction to Air Transport Economics: From Theory to Applications. Burlington, VT: Ashgate). <http://www.ashgate.com/default.aspx?page=637&calcTitle=1&isbn=9781409454878&lang=cy-GB>.

<sup>24</sup> Tuccio, W.A. (2013). Aviation Approach Charts in an iPad World. Journal of Navigation, 66(1). Retrieved from <http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=8777261&fileId=S0373463312000409>.

<sup>25</sup> Tuccio, W.A. (2011). Heuristics to Improve Human Factors Performance in Aviation. Journal of Aviation/Aerospace Education & Research, 20(3). from <http://commons.erau.edu/jaer/vol20/iss3/8>.

commenter requested that appendix G of part 141 be revised to permit flight instructors to use AATDs in their own training. The commenter asserted that if instrument instructors are to teach effectively in ATDs, then it is logical those same instructors should use ATDs during their own training in order to realize economic and safety benefits of ATDs similar to those provided by the new rule under appendix C to part 141, and learn effective ATD training techniques. Yet another commenter suggested expanding the creditable use of ATDs to all certificates—airline transport pilot, commercial, private, flight instructor, etc.

*FAA Response:* The FAA agrees with the commenters and is providing separate regulatory allowances for BATDs and AATDs as described previously and clarifying the amount of creditable time when BATDs and AATDs are used in combination with FSTDs for instrument training. The FAA notes that part 61 provides time allowances for private pilot, commercial pilot, and airline transport pilot in an FSTD that is representative of the aircraft category, class, and type if appropriate. Currently, the FAA approves the use of ATDs for private pilot, commercial pilot, and airline transport pilot certification through the issuance of LOAs under the Administrator's authority in § 61.4(c). The FAA will consider this comment concerning specific regulatory credit for ATDs to meet the requirements for pilot certificates and may address it in other rulemakings as appropriate.

One commenter asserted that current regulations regarding the use of ATDs for instrument proficiency checks under 14 CFR 61.57 is confusing. The commenter noted that § 61.57(d)(1)(i) specifies that the instrument proficiency check must be conducted in an aircraft while the Instrument Practical Test Standard specifies that both FSTDs or AATDs may be used for part or all of the instrument proficiency check. The commenter recommended that the regulations be clarified to correspond to the practical test standard.

*FAA Response:* This comment is outside the scope of the proposed rule. The FAA notes, however, that § 61.57(d)(1)(ii) provides an allowance for use of an FSTD that is representative of the aircraft category when conducting the instrument proficiency check. The FAA will consider this comment concerning the use of an ATD for the instrument proficiency check and the reference in the Instrument Practical Test that allows its use and will address it in other rulemakings as appropriate.

One commenter requested a variety of changes to § 61.57(c) regarding instrument experience and recency for pilots in command. The commenter highlighted differences between current requirements for completing instrument experience using an ATD to maintain instrument experience (§ 61.57(c)(3)); completing instrument recency experience using a combination of an aircraft and a full flight simulator, FTD, and ATD (§ 61.57(c)(4)); and completing instrument experience using a combination of a flight simulator or FTD, and an ATD (§ 61.57(c)(5)).

*FAA Response:* These comments are beyond the scope of this rulemaking. The FAA will consider these comments and may address them in other rulemakings as appropriate.

Finally, one commenter recommended changes to permit ground instructors to use ATDs to train their students.

*FAA Response:* The FAA allows ground instructors certain privileges. This includes training for aeronautical knowledge typically in a classroom environment and authorizing students for knowledge tests. While a ground instructor may use an ATD to illustrate ground training concepts, such training may not be logged to meet the aeronautical experience requirements for certificates and ratings. Providing flight training—or training in FSTDs or ATDs that can substitute for some of the required flight training—is a privilege reserved for flight instructors who have been evaluated during a practical test on the ability to provide flight training. Expanding this privilege to ground instructors is beyond the scope of this rulemaking.

#### 4. Comments Opposing the Proposed Provisions

Three commenters opposed the proposed provisions.

One commenter, who identified himself as a flight instructor, believed that new instrument pilots need the stress, noise, and feeling of the real airplane when forming their habits and acquiring their skills, not the quiet, controlled, sterile atmosphere of a simulator. While the commenter supported the use of simulators later, he did not believe they are appropriate for new pilots.

*FAA Response:* The FAA somewhat disagrees with this commenter's general statement that pilots “. . . need the stress and noise and feeling of the real item when forming their habits and acquiring their skills, not the quiet controlled sterile atmosphere of a SIM.” The FAA contends that training in an ATD allows reduction in unnecessary

distractions during initial training and permits focus on the important fundamental instrument skills and tasks necessary for safe and controlled instrument flight. This includes practicing emergency procedures and other maneuvers that cannot be safely accomplished in an aircraft. Practice in an FSTD or ATD until a pilot performs a particular segment of a procedure or action correctly, before attempting to do the same complex tasks in an aircraft, is an acceptable and desirable practice.

The FAA also contends that because a significant portion of the instrument time must be accomplished in an aircraft, the stress and noise experience and the feeling for the real environment discussed by the commenter will be provided during that time. Additionally, the FAA notes that § 61.65(d)(2)(i) (airplane) and § 61.65(e)(2)(i) (helicopter) currently require that three hours of training must be accomplished in an aircraft within two months of the practical test. The required instrument training on cross country procedures under instrument flight rules, including a flight of 250 nautical miles with at least three different instrument approaches and an instrument approach at each airport, must also be accomplished in an aircraft.

The FAA believes that training in FSTDs and ATDs, when used in conjunction with training in an aircraft, teach an instrument student to trust the appropriate sense, vision, in order to successfully operate an aircraft in low visibility conditions. Training in an ATD reinforces this necessary skill. Any reliance on “sounds or feel” may ultimately lead to loss of control when operating an aircraft in instrument meteorological conditions (IMC). Because ignoring the postural senses involves relying on visual clues, the ATD provides an excellent platform for a pilot to develop this portion of his or her instrument flying skills. A person must use his or her vision and focus on the flight instruments to successfully operate an aircraft, FSTD, or ATD in IMC conditions. The FAA recognizes that training devices do not require motion in order to be approved as an ATD; thus, these devices are limited in that they cannot completely train the pilot to ignore outside sensory perceptions. However, the FAA finds that a pilot can develop this ability during the aeronautical experience that an applicant for an instrument rating must obtain in an aircraft.

Another commenter, who also identified himself as a flight instructor, believed that FTDs and simulators do a good job at pretending to be an airplane in terms of learning procedures, but

they are not an airplane. The commenter believed that an ATD cannot give the true feeling of transitioning from visual meteorological conditions (VMC) to IMC, especially while climbing or turning. The commenter asserted that unless a provision is added to the rule to require the student to have more flight training in IMC conditions (the commenter recommended 5 hours), adding 10 hours of ATD time will only make the instrument pilots of the future less capable of flying in IMC.

*FAA Response:* The FAA agrees with the commenter that these trainers (ATDs) do a great job for learning procedures, but disagrees that ATDs cannot adequately provide for simulated transitions from VMC to IMC. Very often a pilot does not “feel” anything in an aircraft during these transitions. The FAA has evaluated hundreds of ATD visual systems and has found them to have adequate fidelity and capabilities, as required in AC 61–136A, to simulate visibility transition scenarios. In fact, many of the FAA approved visual systems provide for numerous scenarios including flying through multiple layers of clouds and varying visibility conditions. This commenter fails to provide an adequate explanation to support his or her position. Additionally, the commenter’s discussion of FFSs, FTDs and PCATDs is outside the scope of this ATD rulemaking.

The third commenter addressed specific comments relating to a particular ATD. The commenter referenced Redbird ATDs, and asserted that:

[T]heir panels are limiting in the sense that switches are not the same in the simulator as it is [sic] in the airplane. . . . The Redbird simulator does not provide a volume knob for either the COM or NAV which contains the ID mode. This is a required step in order to properly identify a VOR station. . . . The standby instruments is graphically depicted but the position of these instruments does not reflect the real location of where these instruments are installed.<sup>28</sup>

The commenter also expressed concern regarding updated databases to these training devices. The commenter believed that any ATD should be required to have the latest navigation database running on the ATD.

*FAA response:* The FAA notes that the commenter’s discussion is concentrated on the dislike of the functionality of the Redbird trainer, rather than the ATD allowances for the proposed rule. The FAA agrees, however, that ATDs (the FAA assumes

that the commenter is discussing a particular Redbird AATD based on the content of his initial statements) are not identical to the actual aircraft. The FAA emphasizes that, assuming the ATD in question received a LOA from the FAA, it met or exceeded the minimum fidelity and capability requirements specified for such devices in AC 61–136A. ATD fidelity requirements do not require that ATDs be exactly like that of the aircraft. The FAA notes that the Redbird Flight Simulations ATDs the FAA has approved through LOA do provide for the ability to update the database to reflect current instrument approach procedures. Appendix 2 of the AC states: The ATD must have at least a navigational area database that is local to the training facility to allow reinforcement of procedures learned during actual flight in that area. All navigational data must be based on procedures as published per 14 CFR part 97 (STANDARD INSTRUMENT PROCEDURES). The FAA has evaluated many of the Redbird training devices and finds that they meet the standards in AC 61–136A for ATD approval. If one were to prefer greater fidelity or more exacting duplication of certain aircraft configurations, then the FAA would suggest the use of a higher fidelity FAA approved training device such as an FTD or FFS. However, the FAA standards set forth in AC 61–136A are appropriate to training instrument procedures as described in Appendix 4, Training Content and Logging Provisions. This describes what instrument tasks can be successfully taught in ATDs.

##### 5. Comments Opposing the Process

Two commenters expressed strong objections to the path the FAA took regarding this rulemaking. They objected to the withdrawal of the direct final rule, and believed that the adverse comments the FAA received during the comment period for the direct final rule should not have caused the agency to withdraw the rulemaking. They also believed the FAA should have acted more quickly once the original discrepancy between the regulations and policy was identified.

*FAA Response:* Part 11 of title 14 of the Code of Federal Regulations mandates the process and responsibilities associated with rulemaking. The FAA is required to follow those requirements even if viewed as unnecessary or inconvenient by a segment of the public. The Administrative Procedure Act requires the FAA to provide the public an opportunity to comment on proposed rulemakings, allowing the public to

influence or suggest changes to those proposals. The FAA is committed to regulate fairly, promote safety, and works diligently within the confines of the rulemaking process.

##### B. View-Limiting Device

The FAA proposed to revise § 61.65(i)(4) to eliminate the requirement that pilots accomplishing instrument time in an ATD wear a view-limiting device. The FAA emphasizes, however, that a pilot—whether in an aircraft, FFS, FTD, or ATD—may log instrument time only when the pilot is operating solely by reference to the instruments under actual or simulated conditions. If a pilot is using an ATD and the device is providing visual references upon which the pilot is relying, this would not constitute instrument time under § 61.51(g).

*Comments received:* The FAA received six comments from SAFE, NAFI, and four individuals, supporting the elimination of the requirement that pilots accomplishing instrument time in an ATD wear a view-limiting device. SAFE explained its support for removal of the provision, noting that a benefit of using ATDs is simulation of the cockpit environment. SAFE asserted that that benefit is lost when the student is required to wear such a device. SAFE asserted that most students quickly become so immersed in the ATD experience that there is no need for a view-limiting device to further focus them on the instrument panel. All other commenters provided general support and did not explain or further justify their support for removal of this requirement.

*FAA response:* As the FAA stated when discussing the support it received for removing this requirement in the direct final rule, the FAA agrees that it is unnecessary for a student to wear a view-limiting device when using an ATD. The FAA finds that this requirement is not necessary because ATDs do not afford relevant outside references. Therefore, the FAA is revising 14 CFR 61.65(i)(4) to eliminate the requirement that pilots accomplishing instrument time in an ATD wear a view-limiting device.

##### C. Conforming Amendments and Nomenclature Change

While considering these changes, the FAA became aware that other appendices in part 141 reference § 141.41(a) when discussing FFS, and § 141.41(b) when discussing FTDs and ATDs. As this rule consolidates requirements related to FFS and FTDs into § 141.41(a), and adds new paragraph (b) related to ATDs, the FAA

<sup>28</sup> Anonymous, Docket No. FAA–2015–1846–0031.



is correcting cross-references in appendices C, D, E, F, G, J, K, and M.

Further, while considering these regulatory changes, the FAA noted that the nomenclature regarding flight simulators has changed. The definition as found in § 1.1 references a “full flight simulator” whereas the regulations often use the older nomenclature “flight simulator.” Therefore, in the sections the FAA has determined need to be revised as part of the final rule, the FAA is removing the words “flight simulator” wherever they appear and replacing them with the words “full flight simulator.”

## VI. Advisory Circulars and Other Guidance Materials

To further implement this rule, the FAA is revising the following FAA Order: FAA Order 8900.1, Flight Standards Information Management System, Volume 11, Chapter 10, Section 1, (Basic and Advanced Aviation Training Device) Approval and Authorized Use under 14 CFR parts 61 and 141.

## VII. Regulatory Notices and Analyses

### A. Regulatory Evaluation

Changes to Federal regulations must undergo several economic analyses. First, Executive Order 12866 and Executive Order 13563 direct that each Federal agency shall propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs. Second, the Regulatory Flexibility Act of 1980 (Pub. L. 96–354), as codified in 5 U.S.C. 603 *et seq.*, requires agencies to analyze the economic impact of regulatory changes on small entities. Third, the Trade Agreements Act (Pub. L. 96–39), as amended, 19 U.S.C. Chapter 13, prohibits agencies from setting standards that create unnecessary obstacles to the foreign commerce of the United States. In developing U.S. standards, this Trade Act requires agencies to consider international standards and, where appropriate, that they be the basis of U.S. standards. Fourth, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as codified in 2 U.S.C. Chapter 25, requires agencies to prepare a written assessment of the costs, benefits, and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million or more annually (adjusted for inflation with base year of 1995). This portion of the preamble

summarizes the FAA’s analysis of the economic impacts of this final rule.

In conducting these analyses, FAA has determined that this rule: (1) Has benefits that justify its costs; (2) is not an economically “significant regulatory action” as defined in section 3(f) of Executive Order 12866; (3) is not “significant” as defined in DOT’s Regulatory Policies and Procedures; (4) will not have a significant economic impact on a substantial number of small entities; (5) will not create unnecessary obstacles to the foreign commerce of the United States; and (6) will not impose an unfunded mandate on State, local, or tribal governments, or on the private sector by exceeding the threshold identified above. These analyses are summarized below.

Department of Transportation DOT Order 2100.5 prescribes policies and procedures for simplification, analysis, and review of regulations. If the expected cost impact is so minimal that a proposed or final rule does not warrant a full evaluation, this order permits that a statement to that effect and the basis for it be included in the preamble if a full regulatory evaluation of the costs and benefits is not prepared. Such a determination has been made for this final rule. The reasoning for this determination follows.

The provisions included in this rule are either relieving or voluntary. The elimination of the requirement to use a view-limiting device is a relieving provision. The other two provisions are voluntary and cost relieving—additional ATD credit for instrument time for an instrument rating and additional ATD credit for approved instrument courses, if acted upon, is less expensive than flight training time. The FAA made the same cost-benefit determination as part of the direct final rule (79 FR 71634, Dec. 3, 2014) and on this part of the notice of proposed rulemaking (80 FR 34338, Jun. 16, 2015) and received no comments.

Two commenters, both of whom identified themselves as private pilots working toward their instrument ratings, discussed the potential for cost relief provided by the proposed rule. Both commenters estimated that time in an approved simulator with an instructor costs about \$100 per hour, while dual time in an instrument flight rules-certified aircraft is \$200 per hour or more. These commenters asserted that adding an extra 10 hours of simulator time reduces \$1,000 from the overall training cost.

Persons who use the new provisions will do so only if the benefit they will accrue from their use exceeds the costs they might incur to comply. Given the

hundreds of LOAs issued, industry’s high usage of ATDs, and SAFE’s, AOPA’s, and NAFI’s endorsements of ATDs, the change in requirements is likely to be relieving. Benefits will exceed the costs of a voluntary rule if just one person voluntarily complies.

Since this rule will offer a lower cost alternative, will provide regulatory relief for the use of view-limiting devices, and will allow greater voluntary use of ATDs, the expected outcome will be cost relieving to minimal impact with positive net benefits.

### B. Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (Pub. L. 96–354) (RFA) establishes “as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation. To achieve this principle, agencies are required to solicit and consider flexible regulatory proposals and to explain the rationale for their actions to assure that such proposals are given serious consideration.” The RFA covers a wide range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a rule will have a significant economic impact on a substantial number of small entities. If the agency determines that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the RFA provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

Most of the parties affected by this rule will be small businesses such as flight instructors, aviation schools, and fixed base operators. The general lack of publicly available financial information from these small businesses precludes a financial analysis of these small businesses. While there is likely a substantial number of small entities affected, the provisions of this rule are either relieving (directly provides cost relief) or voluntary (provides benefits or costs only if a person voluntarily chooses to use the rule provision). Thus,

the FAA determines that this rule will not have a significant economic impact on a substantial number of small entities. The FAA made the same determination as part of the direct final rule (79 FR 71634, Dec. 3, 2014) and as part of the notice of proposed rulemaking (80 FR 34338, Jun. 16, 2015) and, in both cases, we requested, but did not receive, any comments.

If an agency determines that a rulemaking will not result in a significant economic impact on a substantial number of small entities, the head of the agency may so certify under section 605(b) of the RFA. Therefore, as provided in section 605(b), the head of the FAA certifies that this rulemaking will not result in a significant economic impact on a substantial number of small entities.

### *C. International Trade Impact Assessment*

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standard has a legitimate domestic objective, such as the protection of safety, and does not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards and, where appropriate, that they be the basis for U.S. standards.

The FAA has assessed the potential effect of this rule and determined that it will have only a domestic impact and therefore will not create unnecessary obstacles to the foreign commerce of the United States.

### *D. Unfunded Mandates Assessment*

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of \$100 million or more (in 1995 dollars) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector; such a mandate is deemed to be a “significant regulatory action.” The FAA currently uses an inflation-adjusted value of \$155.0 million in lieu of \$100 million.

This rule does not contain such a mandate. Therefore, the requirements of Title II of the Act do not apply.

### *E. Paperwork Reduction Act*

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. The FAA has determined that there is no new requirement for information collection associated with this rule.

### *F. International Compatibility and Cooperation*

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to conform to International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has reviewed the corresponding ICAO Standards and Recommended Practices and has identified no differences with these regulations.

### *G. Environmental Analysis*

FAA Order 1050.1F identifies FAA actions that are categorically excluded from preparation of an environmental assessment or environmental impact statement under the National Environmental Policy Act in the absence of extraordinary circumstances. The FAA has determined this rulemaking action qualifies for the categorical exclusion identified in paragraph 5–6.6 and involves no extraordinary circumstances.

## **VII. Executive Order Determinations**

### *A. Executive Order 13132, Federalism*

The FAA has analyzed this rule under the principles and criteria of Executive Order 13132, Federalism. The agency has determined that this action will not have a substantial direct effect on the States, or the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government, and, therefore, would not have Federalism implications.

### *B. Executive Order 13211, Regulations That Significantly Affect Energy Supply, Distribution, or Use*

The FAA analyzed this rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use (May 18, 2001). The agency has determined that it will not be a “significant energy action” under the executive order and will not be likely to have a significant adverse effect

on the supply, distribution, or use of energy.

### *C. Executive Order 13609, Promoting International Regulatory Cooperation*

Executive Order 13609, Promoting International Regulatory Cooperation, (77 FR 26413, May 4, 2012) promotes international regulatory cooperation to meet shared challenges involving health, safety, labor, security, environmental, and other issues and to reduce, eliminate, or prevent unnecessary differences in regulatory requirements. The FAA has analyzed this action under the policies and agency responsibilities of Executive Order 13609, and has determined that this action would have no effect on international regulatory cooperation.

## **VIII. Additional Information**

### *A. Availability of Rulemaking Documents*

An electronic copy of rulemaking documents may be obtained from the Internet by—

- Searching the Federal eRulemaking Portal (<http://www.regulations.gov>);
- Visiting the FAA’s Regulations and Policies Web page at [http://www.faa.gov/regulations\\_policies](http://www.faa.gov/regulations_policies), or
- Accessing the Government Publishing Office’s Web page at <http://www.fdsys.gov>.

Copies may also be obtained by sending a request (identified by docket or amendment number of the rule) to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–9677.

All documents the FAA considered in developing this rule, including economic analyses and technical reports, may be accessed from the Internet through the Federal eRulemaking Portal referenced previously.

### *B. Comments Submitted to the Docket*

Comments received may be viewed by going to <http://www.regulations.gov> and following the online instructions to search the docket number for this action. Anyone is able to search the electronic form of all comments received into any of the FAA’s dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.).

### *C. Small Business Regulatory Enforcement Fairness Act*

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) requires FAA to comply with

small entity requests for information or advice about compliance with statutes and regulations within its jurisdiction. A small entity with questions regarding this document may contact its local FAA official, or the person listed under the **FOR FURTHER INFORMATION CONTACT** heading at the beginning of the preamble. To find out more about SBREFA on the Internet, visit [http://www.faa.gov/regulations\\_policies/rulemaking/sbre\\_act/](http://www.faa.gov/regulations_policies/rulemaking/sbre_act/).

**List of Subjects**

*14 CFR Part 61*

Aircraft, Airmen, Aviation safety, Teachers.

*14 CFR Part 141*

Airmen, Educational facilities, Reporting and recordkeeping requirements, Schools.

**The Amendment**

In consideration of the foregoing, the Federal Aviation Administration amends chapter I of title 14, Code of Federal Regulations as follows:

**PART 61—CERTIFICATION: PILOTS, FLIGHT INSTRUCTORS, AND GROUND INSTRUCTORS**

■ 1. The authority citation for part 61 continues to read as follows:

**Authority:** 49 U.S.C. 106(f), 106(g), 40113, 44701–44703, 44707, 44709–44711, 44729, 44903, 45102–45103, 45301–45302.

■ 2. Amend § 61.65 as follows:

■ a. In paragraphs (a)(5), (a)(8)(ii), (c) introductory text, and (h), remove the words “flight simulator” and add in their place the words “full flight simulator”; and,

■ b. Revise paragraph (i) and add paragraph (j).

The revision and addition read as follows:

**§ 61.65 Instrument rating requirements.**

\* \* \* \* \*

(i) *Use of an aviation training device.* A maximum of 10 hours of instrument time received in a basic aviation training device or a maximum of 20 hours of instrument time received in an advanced aviation training device may be credited for the instrument time requirements of this section if—

- (1) The device is approved and authorized by the FAA;
- (2) An authorized instructor provides the instrument time in the device; and
- (3) The FAA approved the instrument training and instrument tasks performed in the device.

(j) Except as provided in paragraph (h)(1) of this section, a person may not credit more than 20 total hours of

instrument time in a full flight simulator, flight training device, aviation training device, or a combination towards the instrument time requirements of this section.

**PART 141—PILOT SCHOOLS**

■ 3. The authority citation for part 141 continues to read as follows:

**Authority:** 49 U.S.C. 106(f), 106(g), 40113, 44701–44703, 44707, 44709, 44711, 45102–45103, 45301–45302.

■ 4. Revise § 141.41 to read as follows:

**§ 141.41 Full flight simulators, flight training devices, aviation training devices, and training aids.**

An applicant for a pilot school certificate or a provisional pilot school certificate must show that its full flight simulators, flight training devices, aviation training devices, training aids, and equipment meet the following requirements:

(a) *Full flight simulators and flight training devices.* Each full flight simulator and flight training device used to obtain flight training credit in an approved pilot training course curriculum must be:

(1) Qualified under part 60 of this chapter, or a previously qualified device, as permitted in accordance with § 60.17 of this chapter; and

(2) Approved by the Administrator for the tasks and maneuvers.

(b) *Aviation training devices.* Each basic or advanced aviation training device used to obtain flight training credit in an approved pilot training course curriculum must be evaluated, qualified, and approved by the Administrator.

(c) *Training aids and equipment.* Each training aid, including any audiovisual aid, projector, mockup, chart, or aircraft component listed in the approved training course outline, must be accurate and relevant to the course for which it is used.

■ 5. In appendix B to part 141, revise paragraph (c) in section 4 to read as follows:

**Appendix B to Part 141—Private Pilot Certification Course**

\* \* \* \* \*

**4. Flight training.** \* \* \*

(c) For use of full flight simulators or flight training devices:

(1) The course may include training in a full flight simulator or flight training device, provided it is representative of the aircraft for which the course is approved, meets the requirements of this paragraph, and the training is given by an authorized instructor.

(2) Training in a full flight simulator that meets the requirements of

§ 141.41(a) may be credited for a maximum of 20 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(3) Training in a flight training device that meets the requirements of § 141.41(a) may be credited for a maximum of 15 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(4) Training in full flight simulators or flight training devices described in paragraphs (c)(2) and (3) of this section, if used in combination, may be credited for a maximum of 20 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less. However, credit for training in a flight training device that meets the requirements of § 141.41(a) cannot exceed the limitation provided for in paragraph (c)(3) of this section.

\* \* \* \* \*

■ 6. In appendix C to part 141, revise paragraph (b) in section 4 to read as follows:

**Appendix C to Part 141—Instrument Rating Course**

\* \* \* \* \*

**4. Flight training.** \* \* \*

(b) For the use of full flight simulators, flight training devices, or aviation training devices—

(1) The course may include training in a full flight simulator, flight training device, or aviation training device, provided it is representative of the aircraft for which the course is approved, meets the requirements of this paragraph, and the training is given by an authorized instructor.

(2) Credit for training in a full flight simulator that meets the requirements of § 141.41(a) cannot exceed 50 percent of the total flight training hour requirements of the course or of this section, whichever is less.

(3) Credit for training in a flight training device that meets the requirements of § 141.41(a), an advanced aviation training device that meets the requirements of § 141.41(b), or a combination of these devices cannot exceed 40 percent of the total flight training hour requirements of the course or of this section, whichever is less. Credit for training in a basic aviation training device that meets the requirements of § 141.41(b) cannot exceed 25 percent of the total training hour requirements permitted under this paragraph.

(4) Credit for training in full flight simulators, flight training devices, and aviation training devices if used in

combination, cannot exceed 50 percent of the total flight training hour requirements of the course or of this section, whichever is less. However, credit for training in a flight training device or aviation training device cannot exceed the limitation provided for in paragraph (b)(3) of this section.

\* \* \* \* \*

■ 7. In appendix D to part 141, revise paragraph (c) in section 4 to read as follows:

**Appendix D to Part 141—Commercial Pilot Certification Course**

\* \* \* \* \*

*4. Flight training.* \* \* \*

(c) For the use of full flight simulators or flight training devices:

(1) The course may include training in a full flight simulator or flight training device, provided it is representative of the aircraft for which the course is approved, meets the requirements of this paragraph, and is given by an authorized instructor.

(2) Training in a full flight simulator that meets the requirements of § 141.41(a) may be credited for a maximum of 30 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(3) Training in a flight training device that meets the requirements of § 141.41(a) may be credited for a maximum of 20 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(4) Training in the flight training devices described in paragraphs (c)(2) and (3) of this section, if used in combination, may be credited for a maximum of 30 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less. However, credit for training in a flight training device that meets the requirements of § 141.41(a) cannot exceed the limitation provided for in paragraph (c)(3) of this section.

\* \* \* \* \*

■ 8. In appendix E to part 141, revise paragraph (b) in section 4 to read as follows:

**Appendix E to Part 141—Airline Transport Pilot Certification Course**

\* \* \* \* \*

*4. Flight training.* \* \* \*

(b) For the use of full flight simulators or flight training devices—

(1) The course may include training in a full flight simulator or flight training device, provided it is representative of the aircraft for which the course is approved, meets the requirements of

this paragraph, and the training is given by an authorized instructor.

(2) Training in a full flight simulator that meets the requirements of § 141.41(a) may be credited for a maximum of 50 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(3) Training in a flight training device that meets the requirements of § 141.41(a) may be credited for a maximum of 25 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(4) Training in full flight simulators or flight training devices described in paragraphs (b)(2) and (3) of this section, if used in combination, may be credited for a maximum of 50 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less. However, credit for training in a flight training device that meets the requirements of § 141.41(a) cannot exceed the limitation provided for in paragraph (b)(3) of this section.

\* \* \* \* \*

■ 9. In appendix F to part 141, revise paragraph (b) in section 4 to read as follows:

**Appendix F to Part 141—Flight Instructor Certification Course**

\* \* \* \* \*

*4. Flight training.* \* \* \*

(b) For the use of flight simulators or flight training devices:

(1) The course may include training in a full flight simulator or flight training device, provided it is representative of the aircraft for which the course is approved, meets the requirements of this paragraph, and the training is given by an authorized instructor.

(2) Training in a full flight simulator that meets the requirements of § 141.41(a), may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(3) Training in a flight training device that meets the requirements of § 141.41(a), may be credited for a maximum of 5 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(4) Training in full flight simulators or flight training devices described in paragraphs (b)(2) and (3) of this section, if used in combination, may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less. However, credit for

training in a flight training device that meets the requirements of § 141.41(a) cannot exceed the limitation provided for in paragraph (b)(3) of this section.

\* \* \* \* \*

■ 10. In appendix G to part 141, revise paragraph (b) in section 4 to read as follows:

**Appendix G to Part 141—Flight Instructor Instrument (For an Airplane, Helicopter, or Powered-Lift Instrument Instructor Rating, as Appropriate) Certification Course**

\* \* \* \* \*

*4. Flight training.* \* \* \*

(b) For the use of full flight simulators or flight training devices:

(1) The course may include training in a full flight simulator or flight training device, provided it is representative of the aircraft for which the course is approved for, meets requirements of this paragraph, and the training is given by an instructor.

(2) Training in a full flight simulator that meets the requirements of § 141.41(a), may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(3) Training in a flight training device that meets the requirements of § 141.41(a), may be credited for a maximum of 5 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(4) Training in full flight simulators or flight training devices described in paragraphs (b)(2) and (3) of this section, if used in combination, may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less. However, credit for training in a flight training device that meets the requirements of § 141.41(b) cannot exceed the limitation provided for in paragraph (b)(3) of this section.

\* \* \* \* \*

■ 11. In appendix J to part 141, revise paragraph (b) in section 4 to read as follows:

**Appendix J to Part 141—Aircraft Type Rating Course, For Other Than an Airline Transport Pilot Certificate**

\* \* \* \* \*

*4. Flight training.* \* \* \*

(b) For the use of full flight simulators or flight training devices:

(1) The course may include training in a full flight simulator or flight training device, provided it is representative of the aircraft for which the course is approved, meets requirements of this

paragraph, and the training is given by an authorized instructor.

(2) Training in a full flight simulator that meets the requirements of § 141.41(a), may be credited for a maximum of 50 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(3) Training in a flight training device that meets the requirements of § 141.41(a), may be credited for a maximum of 25 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(4) Training in the full flight simulators or flight training devices described in paragraphs (b)(2) and (3) of this section, if used in combination, may be credited for a maximum of 50 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less. However, credit training in a flight training device that meets the requirements of § 141.41(a) cannot exceed the limitation provided for in paragraph (b)(3) of this section.

\* \* \* \* \*

■ 12. In appendix K to part 141, revise section 4 to read as follows:

**Appendix K to Part 141—Special Preparation Courses**

\* \* \* \* \*

4. *Use of full flight simulators or flight training devices.* (a) The approved special preparation course may include training in a full flight simulator or flight training device, provided it is representative of the aircraft for which the course is approved, meets requirements of this paragraph, and the training is given by an authorized instructor.

(b) Except for the airline transport pilot certification program in section 13 of this appendix, training in a full flight simulator that meets the requirements of § 141.41(a), may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(c) Except for the airline transport pilot certification program in section 13 of this appendix, training in a flight training device that meets the requirements of § 141.41(a), may be credited for a maximum of 5 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(d) Training in the full flight simulators or flight training devices described in paragraphs (b) and (c) of this section, if used in combination,

may be credited for a maximum of 10 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less. However, credit for training in a flight training device that meets the requirements of § 141.41(a) cannot exceed the limitation provided for in paragraph (c) of this section.

\* \* \* \* \*

■ 13. In appendix M to part 141, revise paragraph (c) of section 4 to read as follows:

**Appendix M to Part 141—Combined Private Pilot Certification and Instrument Rating Course**

\* \* \* \* \*

4. *Flight training.*

\* \* \* \* \*

(c) For use of full flight simulators or flight training devices:

(1) The course may include training in a combination of full flight simulators, flight training devices, and aviation training devices, provided it is representative of the aircraft for which the course is approved, meets the requirements of this section, and the training is given by an authorized instructor.

(2) Training in a full flight simulator that meets the requirements of § 141.41(a) may be credited for a maximum of 35 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(3) Training in a flight training device that meets the requirements of § 141.41(a) or an aviation training device that meets the requirements of § 141.41(b) may be credited for a maximum of 25 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less.

(4) Training in a combination of flight simulators, flight training devices, or aviation training devices, described in paragraphs (c)(2) and (3) of this section, may be credited for a maximum of 35 percent of the total flight training hour requirements of the approved course, or of this section, whichever is less. However, credit for training in a flight training device and aviation training device, that meets the requirements of § 141.41(b), cannot exceed the limitation provided for in paragraph (c)(3) of this section.

\* \* \* \* \*

Issued in Washington, DC, under the authority of 49 U.S.C. 106(f), 44701(a)(5), and 44703(a), on April 4, 2016.

Michael P. Huerta,

Administrator.

[FR Doc. 2016-08388 Filed 4-8-16; 11:15 am]

BILLING CODE 4910-13-P

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 100**

[Docket Number USCG-2015-1126]

RIN 1625-AA08

**Special Local Regulation; Chesapeake Bay, Between Sandy Point and Kent Island, MD**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing special local regulations for certain waters of the Chesapeake Bay. This action is necessary to provide for the safety of life on these navigable waters located between Sandy Point, Anne Arundel County, MD and Kent Island, Queen Anne’s County, MD, during a paddling event on May 14, 2016. This rulemaking will prohibit persons and vessels from being in the regulated area unless authorized by the Captain of the Port Baltimore or Coast Guard Patrol Commander.

**DATES:** This rule is effective from 7:30 a.m. on May 14, 2016 through 12:30 p.m. on May 15, 2016.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2015-1126 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email Mr. Ronald Houck, U.S. Coast Guard Sector Baltimore, MD; telephone 410-576-2674, email [Ronald.L.Houck@uscg.mil](mailto:Ronald.L.Houck@uscg.mil).

**SUPPLEMENTARY INFORMATION:**

**I. Table of Abbreviations**

- CFR Code of Federal Regulations
- COTP Captain of the Port
- DHS Department of Homeland Security
- FR Federal Register
- NPRM Notice of proposed rulemaking
- § Section
- U.S.C. United States Code

## II. Background Information and Regulatory History

On December 28, 2015, ABC Events, Inc. notified the Coast Guard that from 8 a.m. until noon on May 14, 2016, it will be conducting the Bay Bridge Paddle race in the Chesapeake Bay, under and between the north and south spans of the William P. Lane, Jr. (US-50/301) Memorial Bridges, located between Sandy Point, Anne Arundel County, MD and Kent Island, Queen Anne's County, MD. In response, on February 12, 2016, the Coast Guard published a notice of proposed rulemaking (NPRM) titled "Special Local Regulation; Chesapeake Bay, between Sandy Point and Kent Island, MD" in the **Federal Register** (81 FR 7481). There we stated why we issued the NPRM, and invited comments on our proposed regulatory action related to this paddle race. During the comment period that ended March 14, 2016, we received 2 comments. No public meeting was requested, and none was held.

## III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1233. The COTP Baltimore has determined that potential hazards associated with the paddle race on May 14, 2016 will be a safety concern for anyone intending to operate within certain waters of the Chesapeake Bay between Sandy Point and Kent Island, MD. The purpose of this rule is to protect event participants, spectators and transiting vessels on certain waters of the Chesapeake Bay before, during, and after the scheduled event.

## IV. Discussion of Comments, Changes, and the Rule

As noted above, we received 2 comments on our NPRM published on February 12, 2016. There are no changes in the regulatory text of this rule from the proposed rule in the NPRM.

One commenter, the Sailing Club of the Chesapeake, stated that the regulated area for this event would impact its planned annual sailing regatta held on the Chesapeake Bay, between a location south of the south span of the William P. Lane, Jr. (US-50/301) Memorial Bridges and a location north of the north span.

The COTP Baltimore had no prior notifications of this annual sailing regatta in previous years. The Coast Guard will only enforce the regulated area during the enforcement period. However, should the event sponsor develop a schedule that would help predict when and where gaps in the race

course may exist during the event, and vessel traffic would be able to safely transit the regulated area once the Coast Guard Patrol Commander deems it safe to do so, then such actions could be permitted after authorization is obtained.

The second commenter, the Baltimore Port Alliance, stated that, as proposed, the regulated area for this event would block ship access to and from the Port of Baltimore for five hours, and that any restrictions on vessel traffic in or out of the port could result in a significant economic hardship for port stakeholders by disrupting committed schedules. Additionally, the commenter recommended redesigning the paddle race course as to not block the main shipping channel or to change the date of the paddle race to coincide with the annual Great Chesapeake Bay Swim event a month later, so that only one blockage of the main shipping channel would occur.

The Coast Guard agrees that waterway restrictions, when necessary, should be as limited in scope and duration. For this event, enough notice has been provided for persons to schedule, coordinate and adjust their ship schedules. As it currently does with the annual Great Chesapeake Bay Swim event, the Coast Guard will work with the port stakeholders to monitor potential impacts to commercial vessel movements in the vicinity of the event area. Additionally, it is impractical to conduct the events concurrently; as the two events are of different types, each having hundreds of participants occupying the same navigable waters. Since the times for the Great Chesapeake Bay Swim event are also dependent upon tidal current predictions, the possibility exists, should both events be conducted on the same day, the waterway restrictions would last for a significantly longer period of time having a greater impact on the public and the use of the waterway.

This rule establishes special local regulations from 7:30 a.m. until 12:30 p.m. on May 14, 2016, and, if necessary due to inclement weather, from 7:30 a.m. until 12:30 p.m. on May 15, 2016. The regulated area will cover all navigable waters of the Chesapeake Bay between and adjacent to the spans of the William P. Lane Jr. Memorial Bridges from shoreline to shoreline, bounded to the north by a line drawn parallel and 500 yards north of the north bridge span that originates from the western shoreline at latitude 39°00'36" N., longitude 076°23'05" W. and thence eastward to the eastern shoreline at latitude 38°59'14" N., longitude

076°20'00" W., and bounded to the south by a line drawn parallel and 500 yards south of the south bridge span that originates from the western shoreline at latitude 39°00'16" N., longitude 076°24'30" W. and thence eastward to the eastern shoreline at latitude 38°58'38.5" N., longitude 076°20'06" W. The duration of the regulated area is intended to ensure the safety of vessels and these navigable waters before, during, and after the event, currently scheduled to being at 8 a.m. and last until noon. Except for Bay Bridge Paddle participants, no vessel or person will be permitted to enter the regulated area without obtaining permission from the COTP Baltimore or designated Coast Guard Patrol Commander.

## V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

### A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size and duration of the regulated area, which would impact a small designated area of the Chesapeake Bay for only 5 hours. Although the regulated area cuts off one portion of the Chesapeake Bay from the other, the closure is temporary, and notice has been provided well in advance to permit mariners to plan their transit. The Coast Guard would issue a Broadcast Notice to Mariners via VHF-FM marine channel 16 about the status of the regulated area. Moreover, the rule would allow vessels to seek permission to enter the regulated area, and vessel traffic would be able to safely transit the regulated area once the Coast Guard Patrol Commander deems it safe to do so.

### B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the regulated area may be small entities, for the reasons stated in section IV.A above this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

### C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

### D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of

power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

### E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

### F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves implementation of regulations within 33 CFR part 100 applicable to organized marine events on the navigable waters of the United States that could negatively impact the safety of waterway users and shore side activities in the event area lasting for 5 hours. The category of water activities includes but is not limited to sail boat regattas, boat parades, power boat racing, swimming events, crew racing, canoe and sail board racing. It is categorically excluded from further review under paragraph 34(h) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion

Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

### G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

### List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

### PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for part 100 continues to read as follows:

**Authority:** 33 U.S.C. 1233.

■ 2. Add a temporary § 100.35–T05–1126 to read as follows:

#### § 100.35–T05–1126 Special Local Regulation; Chesapeake Bay, between Sandy Point and Kent Island, MD.

(a) *Regulated area.* The following location is a regulated area: All navigable waters of the Chesapeake Bay between and adjacent to the spans of the William P. Lane Jr. Memorial Bridges from shoreline to shoreline, bounded to the north by a line drawn parallel and 500 yards north of the north bridge span that originates from the western shoreline at latitude 39°00′36″ N., longitude 076°23′05″ W. and thence eastward to the eastern shoreline at latitude 38°59′14″ N., longitude 076°20′00″ W., and bounded to the south by a line drawn parallel and 500 yards south of the south bridge span that originates from the western shoreline at latitude 39°00′16″ N., longitude 076°24′30″ W. and thence eastward to the eastern shoreline at latitude 38°58′38.5″ N., longitude 076°20′06″ W. All coordinates reference Datum NAD 1983.

(b) *Definitions.* (1) *Captain of the Port Baltimore* means the Commander, U.S. Coast Guard Sector Baltimore, Maryland or any Coast Guard commissioned, warrant or petty officer who has been authorized by the Captain of the Port to act on his behalf.

(2) *Coast Guard Patrol Commander* means a commissioned, warrant, or petty officer of the U.S. Coast Guard who has been designated by the Commander, Coast Guard Sector Baltimore.

(3) *Official Patrol* means any vessel assigned or approved by Commander, Coast Guard Sector Baltimore with a commissioned, warrant, or petty officer on board and displaying a Coast Guard ensign.

(4) *Participant* means all persons and vessels participating in the Bay Bridge Paddle event under the auspices of the Marine Event Permit issued to the event sponsor and approved by Commander, Coast Guard Sector Baltimore.

(c) *Special local regulations.* (1) The Coast Guard Patrol Commander may forbid and control the movement of all vessels and persons, including event participants, in the regulated area. When hailed or signaled by an official patrol, a vessel or person in the regulated area shall immediately comply with the directions given. Failure to do so may result in expulsion from the area, citation for failure to comply, or both. The Coast Guard Patrol Commander may terminate the event, or the operation of any support vessel participating in the event, at any time it is deemed necessary for the protection of life or property.

(2) Except for participants and vessels already at berth, mooring, or anchor, all persons and vessels within the regulated area at the time it is implemented are to depart the regulated area.

(3) Persons desiring to transit the regulated area must first obtain authorization from the Captain of the Port Baltimore or Coast Guard Patrol Commander. Prior to the enforcement period, to seek permission to transit the area, the Captain of the Port Baltimore can be contacted at telephone number 410-576-2693 or on Marine Band Radio, VHF-FM channel 16 (156.8 MHz). During the enforcement period, to seek permission to transit the area, the Coast Guard Patrol Commander can be contacted on Marine Band Radio, VHF-FM channel 16 (156.8 MHz) for direction.

(4) The Coast Guard may be assisted in the patrol and enforcement of the regulated area by other Federal, State, and local agencies. The Coast Guard Patrol Commander and official patrol vessels enforcing this regulated area can be contacted on marine band radio VHF-FM channel 16 (156.8 MHz) and channel 22A (157.1 MHz).

(5) The Coast Guard will publish a notice in the Fifth Coast Guard District Local Notice to Mariners and issue a marine information broadcast on VHF-

FM marine band radio announcing specific event date and times.

(d) *Enforcement period.* This section will be enforced from 7:30 a.m. until 12:30 p.m. on May 14, 2016, and, if necessary due to inclement weather, from 7:30 a.m. until 12:30 p.m. on May 15, 2016.

Dated: March 31, 2016.

**Lonnie P. Harrison, Jr.,**

*Captain, U.S. Coast Guard, Captain of the Port Baltimore.*

[FR Doc. 2016-08380 Filed 4-11-16; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 117

[Docket No. USCG-2016-0293]

#### Drawbridge Operation Regulation; Connecticut River, East Haddam, CT

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of deviation from drawbridge regulation.

**SUMMARY:** The Coast Guard has issued a temporary deviation from the operating schedule that governs the Route 82 Bridge across the Connecticut River, mile 16.8, at East Haddam, Connecticut. This deviation is necessary to allow the bridge owner to perform emergency repairs at the bridge.

**DATES:** This deviation is effective from 7 a.m. on April 18, 2016 to 3 p.m. on June 30, 2016.

**ADDRESSES:** The docket for this deviation, [USCG-2016-0293] is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary deviation, call or email Judy Leung-Yee, Project Officer, First Coast Guard District, telephone (212) 514-4330, email [judy.k.leung-yee@uscg.mil](mailto:judy.k.leung-yee@uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Route 82 Bridge, mile 16.8, across the Connecticut River, has a vertical clearance in the closed position of 22 feet at mean high water and 25 feet at mean low water. The existing bridge operating regulations are found at 33 CFR 117.205(c).

The waterway is transited by seasonal recreational traffic and some commercial barge traffic of various sizes.

The bridge owner, Connecticut Department of Transportation, requested a temporary deviation from the normal operating schedule to perform emergency repairs at the bridge.

Under this temporary deviation, the Route 82 Bridge shall open on signal from April 18, 2016 to June 30, 2016, Monday to Friday between 7 a.m. and 3 p.m. if at least two-hour notice is given by calling the number posted at the bridge.

Vessels able to pass under the bridge in the closed position may do so at anytime. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass.

The Coast Guard will inform the users of the waterways through our Local Notice and Broadcast to Mariners of the change in operating schedule for the bridge so that vessel operations can arrange their transits to minimize any impact caused by the temporary deviation.

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

Dated: April 6, 2016.

**C.J. Bisignano,**

*Supervisory Bridge Management Specialist, First Coast Guard District.*

[FR Doc. 2016-08296 Filed 4-11-16; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 9

#### RIN 2900-AN40

#### Servicemembers' Group Life Insurance and Veterans' Group Life Insurance—Slayer's Rule Exclusion

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Final rule.

**SUMMARY:** The Department of Veterans Affairs adopts as final, without change, the final rule seeking comments published on October 3, 2012, amending its regulations governing Servicemembers' Group Life Insurance (SGLI) and Veterans' Group Life Insurance (VGLI). Specifically, this rule prohibits paying insurance proceeds because of the death of a person (decedent) whose life was insured under SGLI or VGLI, or paying a SGLI Traumatic Injury Protection (TSGLI) benefit to a person (slayer) convicted of



intentionally and wrongfully killing the decedent or determined in a civil proceeding to intentionally and wrongfully killing the decedent. This prohibition of payment also applies to any family member of the slayer who is not related to the decedent and to any person who assisted the slayer in causing the death of the decedent. Additionally, the term “domestic partner” is removed from the definition of “member of the family”.

**DATES:** *Effective Date:* This final rule is effective April 12, 2016.

**FOR FURTHER INFORMATION CONTACT:**

Monica Keitt, Attorney/Advisor, Department of Veterans Affairs, Insurance Center, 5000 Wissahickon Avenue, Philadelphia, PA 19144, (215) 842-2000, ext. 2905. (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:** On October 3, 2012, VA published in the **Federal Register** (77 FR 60304) a final rule seeking comments that amended 38 CFR 9.1 and 9.5 to prevent certain persons from receiving insurance proceeds through the SGLI, VGLI, or TSGLI program as beneficiaries. The rule prevents payment of proceeds to any persons (slayer) found criminally or civilly liable for intentionally and wrongfully killing a person (decedent) insured under SGLI or VGLI or who is eligible for a TSGLI benefit. It also prevents payment to any persons found criminally or civilly liable for assisting or aiding such a slayer and any member of the slayer’s family who is not related to the decedent by blood, legal adoption, or marriage. In a proposed rule published on December 13, 2011, (76 FR 77455), “domestic partner” was added to the definition of “member of the family” in 38 CFR 9.1(l) for the purposes of 38 CFR 9.5(e) to prevent unjust enrichment of persons who are domestic partners of the slayer based on the rationale that these persons are often in relationships with the slayer equivalent to being “relatives” of the slayer. Then, in the final rule published on October 3, 2012, VA removed the term “domestic partner” from the definition of “member of the family” for the purposes of § 9.5(e) “due to the unsettled legal landscape surrounding the recognition of such partnerships”. 77 FR at 60305. VA explained that because recognition of the legality of such relationships varies from state to state, VA determined that including such partnerships in this part would cause an undue administrative burden. Interested persons were invited to submit, on or before December 3, 2012, written comments regarding removing the term “domestic partner” from the

definition. VA received comments from three individuals objecting to removing the term.

**Public Comments Regarding Removal of the Term “Domestic Partner”**

Two commenters noted that some federal agencies, including VA, have expanded their program definitions of family members to include domestic partners. One commenter noted that a Presidential Memorandum directed Federal agencies to extend certain benefits currently available to Federal employees’ spouses and their children to Federal employees’ same-sex domestic partners and their children. See Presidential Memorandum—Extension of Benefits to Same-Sex Domestic Partners of Federal Employees (June 2, 2010). One commenter noted that other Federal agencies, such as the General Services Administration, have established through regulations definitions of family members that include domestic partners.

One commenter also stated that failure to include domestic partners in the definition of “member of the family” would allow a same-sex domestic partner of a slayer to circumvent the regulation, while prohibiting heterosexual spouses of a slayer from receiving insurance benefits. This commenter also stated that “. . . [i]ncluding domestic partners is important to prevent an aberration in the rule . . .” and to “. . . prevent[ ] the unjust collection of life insurance benefits.”

Two commenters noted that the Department of Defense changed its military policies regarding openly gay and lesbian servicemembers, thus VA should change its policy here, since VA is a related agency that serves servicemembers and their families.

Two commenters also noted that VA has recognized domestic partnerships in other VA related matters. Specifically, the commenters pointed to VA’s hospital visitation policy allowing persons designated as domestic partners to be beneficiaries for SGLI and VGLI benefits.

Lastly, one commenter noted that removal of the term domestic partner “sends a message that VA may not be willing to recognize domestic partners as family in any context.” However, recent Supreme Court cases and the United States Attorney General help to clarify legally accepted definitions. On June 26, 2013, the Supreme Court in *United States v. Windsor*, 133 S. Ct. 2675 (2013), held that the Defense of Marriage Act (DOMA), Sec. 3, Public Law 104–199, 110 Stat. 2419, defining “marriage” and “spouse” for purposes

of federal law to preclude recognition of marriages of same-sex couples, is unconstitutional because it violates Fifth Amendment principles by discriminating against same-sex couples who are legally married under state law. VA administers federal benefits and programs that require defining “spouse” and “surviving spouse.” For purposes of VA benefits, 38 U.S.C. 101(3) and 101(31) define “surviving spouse” and “spouse” as persons “of the opposite sex.” However these definitions (codified separately from DOMA) were not specifically addressed in the Supreme Court’s *Windsor* decision. Then on September 4, 2013, the United States Attorney General announced that the President had directed the Executive Branch to cease enforcement of 38 U.S.C. 101(3) and 101(31), to the extent they preclude provision of veterans’ benefits to same-sex married couples, but was silent as to “domestic partners”. Accordingly, VA ceased to enforce the definitional provisions in title 38 to the extent they preclude provision of veterans’ benefits, including SGLI, VGLI, and TSGLI benefits, to same-sex married couples. As a result, VA administers spousal and survivors’ benefits to same-sex married couples, provided the marriages meet the requirements of 38 U.S.C. 103(c). Section 103(c) provides that, for purposes of all laws administered by VA, a veteran’s marriage is to be recognized according to the law of the place where the parties resided at the time of the marriage or the law of the place where the parties resided when the right to benefits accrued.

On June 26, 2015, the Supreme Court in *Obergefell v. Hodges*, 135 S. Ct. 2584 (2015), held that the Fourteenth Amendment of the U.S. Constitution requires a state to license a marriage between two people of the same sex and to recognize a marriage between two people of the same sex when their marriage was lawfully licensed and performed out-of-state, but again did not include “domestic partners”. Accordingly, VA now recognizes all lawful same-sex marriages for VA purposes.

In light of *Windsor* and *Obergefell*, VA no longer enforces the title 38 definitions of “spouse” and “surviving spouse” to the extent that they exclude the recognition of same-sex married couples. However, in other words, VA provides benefits to all same-sex “spouses” and “surviving spouses” of veterans or, in the case of insurance benefits, of servicemembers or former servicemembers, to the extent they are otherwise eligible, based on a State’s recognition of the validity of the

marriage. However, VA does not currently provide all the same spousal benefits to either same-sex or opposite-sex domestic partners of veterans or, in the case of insurance benefits, of servicemembers or former servicemembers.

The comments we received essentially concern equal treatment of same-sex couples and opposite-sex couples. The Supreme Court in *Windsor* and *Obergefell* accomplished that with regard to marriages but did not address other relationships, such as domestic partnerships or legal unions. Thus, those decisions do not affect VA's decision to remove "domestic partner" from the § 9.1(l) definition of "member of the family." *Windsor* and *Obergefell* have not changed the unsettled legal landscape surrounding the recognition of both same-sex and opposite-sex domestic partnerships. For instance, recognition of the legality of domestic partnerships continues to vary from state to state and, because the term is not used consistently from state to state, there remains inter-jurisdictional confusion regarding use of that term. Therefore, including domestic partnerships, of both same-sex couples and opposite-sex couples, in the definition of "member of the family" in § 9.1(l) would cause an undue administrative burden in applying 38 CFR 9.5(e).

Two commenters suggested that VA could establish its own uniform definition of "domestic partnership" rather than relying upon varying state laws. The commenters pointed to regulations of other federal agencies establishing definitions of "domestic partnerships." We decline that suggestion for the following reasons. First, it would create inconsistency between VA's recognition of marriages, which, under 38 U.S.C. 103(c), is expressly based on state laws recognizing marriages, and VA's recognition of domestic partnerships or civil unions, which, under the commenters' suggestion, could be inconsistent with state laws governing recognition of such relationships. Second, defining the term "domestic partner" without regard to state law would require VA to undertake difficult and burdensome fact-finding actions under imprecise standards. We note that the other agency regulations cited by the commenters are varied and often employ vague and subjective standards, such as requiring a finding that the individuals are in a "committed relationship" or "agree to be responsible for each other's common welfare," which may lead to inconsistency in application. Third, VA likely would face

difficulty in developing evidence to establish that such standards are satisfied. The primary evidence of whether individuals were in a "committed relationship" often may be the testimony of the individuals in that relationship. Such evidence may be difficult to obtain or may be unreliable in relation to this rule, which, unlike the examples cited by the commenters, would preclude, rather than extend, benefits based upon the relationship.

Regarding a comment that excluding domestic partnerships from the definition of "family members" may result in unjust enrichment to certain domestic partners of persons causing the death of an insured individual, we acknowledge that this is a potential consequence of the rule. However, the alternative standards we have considered, including following varied state laws governing domestic partnerships or establishing our own definition of "domestic partnership" based in part on subjective standards, would also pose a risk of yielding inconsistent results and possibly allowing unjust enrichment to certain individuals in specific cases. We believe we have appropriately balanced those risks with the interests of clarity, consistency, and administrative efficiency in determinations made under this rule. Accordingly, VA declines to make any changes to this rulemaking based on the above comments.

#### **Justification for the Final Rule Seeking Comments**

One commenter noted that VA failed to provide good cause for dispensing with advance public notice and the opportunity for public comment. Specifically, the commenter stated that VA failed to provide a sufficient justification for citing "public interest" and "impracticability" as reasons for proceeding without providing an opportunity for advance notice and comment. We correctly identified public interest as grounds for proceeding with final rule seeking comments, but could have been clearer in explaining that it would have been against the public's interest to delay implementation of the slayer provisions for the purpose of receiving comments on the definition of "member of the family." We designed the rule to prevent slayers from benefiting from their wrongdoing, and any delay in finalizing the rule would have potentially permitted slayers to receive benefits in violation of public policy and ethical concerns. Nonetheless, on October 3, 2012, VA provided the public formal notice and an opportunity to comment on the

exclusion of the term "domestic partner" through publication of the final rule seeking comments. VA received comments on the exclusion, and we considered those comments in issuing this final rule. Additionally, we note that, since the publication of the October 3, 2012, rule, no case has been affected by the exclusion of "domestic partner" from the definition of "member of the family."

Based on the rationale set forth above and the preamble in the final rule seeking comments, VA adopts, without change, the rule published on October 3, 2012, at 77 FR 60304.

#### **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 an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This final rule will have no such effect on State, local, and tribal governments or on the private sector.

#### **Paperwork Reduction Act**

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

#### **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 Fiscal Year to Date."

#### Regulatory Flexibility Act

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

#### Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance number and title for the program affected by this document is 64.103, Life Insurance for 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. On April 6, 2016, Robert D. Snyder, Chief of Staff, Department of Veterans Affairs, approved this document for publication.

#### List of Subjects in 38 CFR Part 9

Life insurance, Military personnel, Veterans.

Dated: April 7, 2016.

**William F. Russo,**

*Director, Office of Regulation Policy & Management, Office of the General Counsel, Department of Veterans Affairs.*

For the reasons set forth out in the preamble, VA adopts the final rule seeking comments published in the **Federal Register** at 77 FR 60304 on October 3, 2012, as final without change.

[FR Doc. 2016–08381 Filed 4–11–16; 8:45 am]

**BILLING CODE 8320–01–P**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

**[EPA–R08–OAR–2015–0493; FRL–9942–84–Region 8]**

#### Approval and Promulgation of Air Quality Implementation Plans; Colorado; Revisions to Common Provisions and Regulation Number 3; Corrections

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Correcting amendments.

**SUMMARY:** The Environmental Protection Agency (EPA) published in the January 25, 2016 **Federal Register** a document concerning the approval of Air Quality State Implementation Plan (SIP) revisions to Colorado Common Provisions and Regulation Number 3. Inadvertently, the publication date of January 25, 2016 was listed in the regulatory text under the heading "EPA Effective Date" instead of the effective date of February 24, 2016. The correct EPA effective date was provided in the rule preamble. This document corrects the "EPA Effective Date" within the regulatory text to February 24, 2016.

**DATES:** This correcting amendment is effective on April 12, 2016.

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

**SUPPLEMENTARY INFORMATION:** The EPA published a document in the January 25, 2016 **Federal Register** (81 FR 3963) concerning air quality SIP revisions to Colorado's Common Provisions and

Regulation Number 3. These revisions became effective on February 24, 2016 as correctly noted in the rule preamble. The "EPA Effective Date" within the regulatory text for this action was inadvertently listed as January 25, 2016. This correction revises the "EPA Effective Date" within the regulatory text to reflect the actual EPA effective date of February 24, 2016.

#### List of Subjects in 40 CFR Part 52

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

Accordingly, 40 CFR part 52 is corrected by making the following correcting amendments:

#### 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 G—Colorado

■ 2. Section 52.320(c), the Table is amended:

- a. Under "5 CCR 1001–02 Common Provision Regulation" by revising entries "I" and "II";
- b. Under "5 CCR 1001–05, Regulation Number 3, Part A, Concerning General Provisions Applicable to Reporting and Permitting" by revising entries "I", "II", "V", "VI", "VIII", and "Appendix B";
- c. Under "5 CCR 1001–05, Regulation Number 3, Part B, Concerning Construction Permits" by revising entries "II" and "III"; and
- d. Under "5 CCR 1001–05, Regulation Number 3, Part D, Concerning Major Stationary Source New Source Review and Prevention of Significant Deterioration" by revising entries "I", "II", "III", "V", "VI", "X", "XIII", "XIV", and "XV".

The revisions read as follows:

#### § 52.320 Identification of plan.

\* \* \* \* \*

(c) \* \* \*

Title	State effective date	EPA effective date	Final rule citation/date	Comments
*	*	*	*	*
<b>5 CCR 1001–02, Common Provisions Regulation</b>				
I. Definitions, Statement of Intent, and General Provisions Applicable to all Emission Control Regulations adopted by the Colorado Air Quality Control Commission.	1/30/10 12/15/10	2/24/16	81 FR 3963, 1/25/16	Except I.G. Definitions, “Construction” and “Day”
II. General .....	1/30/10	2/24/16	81 FR 3963, 1/25/16	Except II.I.; II.J.5.
*	*	*	*	*
<b>5 CCR 1001–05, Regulation Number 3, Part A, Concerning General Provisions Applicable to Reporting and Permitting</b>				
I. Applicability .....	12/15/2010 12/15/2011 2/15/2013	2/24/16	81 FR 3963, 1/25/16	Except I.B.31.c. and I.B.31.d.
II. Air Pollutant Emission Notice (APEN) Requirements .....	12/15/2010 12/15/2011 2/15/2013	2/24/16	81 FR 3963, 1/25/16	
*	*	*	*	*
V. Certification and Trading of Emission Reduction Credits Offset and Netting Transactions.	12/15/2010 2/15/2013	2/24/16	81 FR 3963, 1/25/16	
VI. Fees .....	12/15/2010 2/15/2013	2/24/16	81 FR 3963, 1/25/16	
*	*	*	*	*
VIII. Technical Modeling and Monitoring Requirements .....	12/15/2010	2/24/16	81 FR 3963, 1/25/16	
*	*	*	*	*
Appendix B, Non-criteria Reportable Pollutants (Sorted by BIN).	12/15/2010 2/15/2013	2/24/16	81 FR 3963, 1/25/16	
<b>5 CCR 1001–05, Regulation Number 3, Part B, Concerning Construction Permits</b>				
*	*	*	*	*
II. General Requirements for Construction Permits .....	12/15/2010 12/15/2011	2/24/16	81 FR 3963, 1/25/16	
III. Construction Permit Review Procedures .....	12/15/2010 12/15/2011 2/15/2013	2/24/16	81 FR 3963, 1/25/16	
<b>5 CCR 1001–05, Regulation Number 3, Part D, Concerning Major Stationary Source New Source Review and Prevention of Significant Deterioration</b>				
I. Applicability .....	12/15/2010 2/15/2013	2/24/16	81 FR 3963, 1/25/16	
II. Definitions .....	12/15/2010 12/15/2011 2/15/2013	2/24/16	81 FR 3963, 1/25/16	Except II.A.26.d., the phrase “and only PM <sub>2.5</sub> emissions can be used to evaluate the net emissions increase for PM <sub>2.5</sub> ”
III. Permit Review Procedures .....	12/15/2011	2/24/16	81 FR 3963, 1/25/16	
*	*	*	*	*
V. Requirements Applicable to Nonattainment Areas .....	12/15/2011 2/15/2013	2/24/16	81 FR 3963, 1/25/16	

Title	State effective date	EPA effective date	Final rule citation/date	Comments
VI. Requirements applicable to attainment and unclassifiable areas and pollutants implemented under Section 110 of the Federal Act (Prevention of Significant Deterioration Program).	12/15/2010 12/15/2011 2/15/2013	2/24/16	81 FR 3963, 1/25/16	Except for VI.A.1.c., the phrase "for phases that commence construction more than 18 months after the initial granting of the permit"; VI.A.2., the phrase "either Section VI.A.2.a. or b., as clarified for any relevant air pollutant, in Section VI.A.2.c."; VI.A.2.c.; VI.B.3.a.(iii) in reference to PM <sub>2.5</sub> monitoring exemption; and VI.B.3.d.
* * * * *				
X. Air Quality Limitations .....	12/15/2011	2/24/16	81 FR 3963, 1/25/16	
* * * * *				
XIII. Federal Class I Areas .....	12/15/2011	2/24/16	81 FR 3963, 1/25/16	
XIV. Visibility .....	12/15/2010	2/24/16	81 FR 3963, 1/25/16	
XV. Actuals PALs .....	12/15/2010	2/24/16	81 FR 3963, 1/25/16	
* * * * *				

\* \* \* \* \*

Dated: March 24, 2016.

**Shaun L. McGrath,**

*Regional Administrator, Region 8.*

[FR Doc. 2016-08274 Filed 4-11-16; 8:45 am]

**BILLING CODE 6560-50-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[EPA-R10-OAR-2016-0003; FRL-9944-83-Region 10]

**Approval and Promulgation of Implementation Plans; Spokane, Washington: Second 10-Year PM<sub>10</sub> Limited Maintenance Plan**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is approving the limited maintenance plan submitted on January 4, 2016, by the State of Washington for the Spokane area, which includes the cities of Spokane, Spokane Valley, Millwood and surrounding unincorporated areas in Spokane County, Washington. This plan addresses the second 10-year maintenance period for particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM<sub>10</sub>). A limited maintenance plan is used to meet Clean

Air Act requirements for formerly designated nonattainment areas that meet certain qualification criteria. The EPA determined that Washington's submittal meets the limited maintenance plan criteria. The Spokane area currently has monitored PM<sub>10</sub> levels well below the National Ambient Air Quality Standards (NAAQS) and levels have not increased since the area was redesignated to attainment in 2005. The EPA is also approving minor updates to the Spokane Regional Clean Air Agency (SRCAA) regulations controlling PM<sub>10</sub> related to the maintenance plan.

**DATES:** This final rule is effective May 12, 2016.

**ADDRESSES:** The EPA has established a docket for this action under Docket ID No. EPA-R10-OAR-2016-0003. All documents in the docket are listed on the <http://www.regulations.gov> Web site. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the Air Programs Unit, Office of Air, Waste and Toxics, EPA Region 10, 1200 Sixth Avenue, Seattle, WA, 98101. The

EPA requests that if at all possible, 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:** For information please contact Jeff Hunt at (206) 553-0256, [hunt.jeff@epa.gov](mailto:hunt.jeff@epa.gov), or by using the above EPA, Region 10 address.

**SUPPLEMENTARY INFORMATION:**

**Table of Contents**

- I. Background Information
- II. Final Action
- III. Incorporation by Reference
- IV. Statutory and Executive Orders Review

**I. Background Information**

On February 26, 2016, the EPA proposed to approve the limited maintenance plan submitted by the State of Washington, on January 4, 2016, for the Spokane PM<sub>10</sub> area, including minor regulatory changes associated with the limited maintenance plan (81 FR 9793). An explanation of the Clean Air Act requirements, a detailed analysis of the submittal, and the EPA's reasons for proposing approval were provided in the notice of proposed rulemaking, and will not be restated here. The public comment period for this proposed rule ended on March 28, 2016. The EPA received no comments on the proposal.

## II. Final Action

The EPA is approving the limited maintenance plan submitted by the State of Washington, on January 4, 2016, for the Spokane PM<sub>10</sub> area. The EPA's approval of this limited maintenance plan satisfies the Clean Air Act requirements for the second 10-year period in the Spokane PM<sub>10</sub> area. Additionally, the EPA is approving and incorporating by reference updated versions of supporting regulations, specifically SRCAA Regulation I, sections 6.05, 6.14, and 6.15. These regulatory changes update and clarify the general PM<sub>10</sub> control measures, including minor revisions to the emission reduction strategies for both paved and unpaved roads.

## III. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the regulations described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents generally available electronically through <http://www.regulations.gov> and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

## IV. Statutory and Executive Orders Review

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

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because this action does not involve technical standards; and
- does not provide the 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 it will not impose substantial direct costs on tribal governments or preempt tribal law. This SIP revision is not approved to apply in Indian reservations in the State or any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. Consistent with EPA policy, the EPA provided a consultation opportunity to the Spokane Tribe in a letter dated May 21, 2015. The EPA did not receive a request for consultation.

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. The EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal**

**Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 13, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. See section 307(b)(2).

## List of Subjects in 40 CFR Part 52

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

Dated: April 1, 2016.

**Dennis J. McLerran**,

*Regional Administrator, Region 10.*

For the reasons set forth in the preamble, 40 CFR part 52 is amended as follows:

## PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

### Subpart WW—Washington

- 2. In § 52.2470:
  - a. Amend paragraph (c), Table 9 "Additional Regulations Approved for Spokane Regional Clean Air Agency (SRCAA) Jurisdiction", by revising entries "6.05", "6.14", and "6.15".
  - b. Amend paragraph (e), Table 2 "Attainment, Maintenance, and Other Plans", by adding an entry to the end of the table.

The revisions and addition read as follows:

### § 52.2470 Identification of plan.

\* \* \* \* \*  
(c) \* \* \*

TABLE 9—ADDITIONAL REGULATIONS APPROVED FOR THE SPOKANE REGIONAL CLEAN AIR AGENCY (SRCAA) JURISDICTION

[Applicable in Spokane County, excluding facilities subject to Energy Facilities Site Evaluation Council (EFSEC) jurisdiction, Indian reservations and any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, and facilities subject to the applicability sections of WAC 173–400–700, 173–405–012, 173–410–012, and 173–415–012]

State/local citation	Title/subject	State/local effective date	EPA approval date	Explanations
<b>Spokane Regional Clean Air Agency Regulations</b>				
<b>Regulation I—Article VI—Emissions Prohibited</b>				
6.05	Particulate Matter and Preventing Particulate Matter from Becoming Airborne.	04/10/04	04/12/16 [Insert <b>Federal Register</b> citation].	Except 6.05(A).
6.14	Standards for Control of Particulate Matter on Paved Surfaces.	06/03/07	04/12/16 [Insert <b>Federal Register</b> citation].	
6.15	Standards for Control of Particulate Matter on Unpaved Roads.	06/03/07	04/12/16 [Insert <b>Federal Register</b> citation].	
*	*	*	*	*

\* \* \* \* \* (e) \* \* \*

TABLE 2—ATTAINMENT, MAINTENANCE, AND OTHER PLANS

Name of SIP Provision	Applicable geographic or nonattainment area	State submittal date	EPA approval date	Explanations
*	*	*	*	*
Particulate Matter (PM <sub>10</sub> ) 2nd 10-Year Limited Maintenance Plan.	Spokane .....	1/4/16	4/12/16 [Insert <b>Federal Register</b> citation].	

[FR Doc. 2016–08272 Filed 4–11–16; 8:45 am]  
 BILLING CODE 6560–50–P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA–HQ–OPP–2014–0449; FRL–9944–11]

**1,2-Propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]-; Exemption From the Requirement of a Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- (CAS Reg. No. 70280–68–1) when used as an inert ingredient (antifoaming agent) in pesticide formulations applied to growing crops at a maximum concentration not to exceed 5% by weight. Exponent, on behalf of ISK Biosciences submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an

exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]-.

**DATES:** This regulation is effective April 12, 2016. Objections and requests for hearings must be received on or before June 13, 2016, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2014–0449, 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>.

**FOR FURTHER INFORMATION CONTACT:** Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: [RDfRNtices@epa.gov](mailto:RDfRNtices@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this action apply to me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How can I get electronic access to other related information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the OCSPP test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

*C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0449 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before June 13, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0449, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about

dockets generally, is available at <http://www.epa.gov/dockets>.

## II. Petition for Exemption

In the **Federal Register** of April 6, 2015 (80 FR 18327) (FRL-9924-00), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-10699) by Exponent, on behalf of ISK Biosciences, 7470 Auburn Road, Suite A, Concord, OH 44077. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyloxy)-1-disiloxyanyl]propoxy]- (CAS Reg. No. 70280-68-1) when used as an inert ingredient (antifoaming agent) in pesticide formulations applied to growing crops at a maximum concentration not to exceed 10% in formulation. That document referenced a summary of the petition prepared by Exponent, the petitioner, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the limitation on the maximum concentration in the pesticide formulation from 10% to 5%. This limitation is based on the Agency's risk assessment which can be found at <http://www.regulations.gov> in document, "1,2-Propanediol, 3-[3-[1,3,3,3,3-tetramethyl-1-[(trimethylsilyloxy)-1-disiloxyanyl]propoxy]-; Human health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pre-harvest Pesticide Products Under 40 CFR 180.920" in docket ID number EPA-HQ-OPP-2014-0449.

## III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the

ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

## IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . ."

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-



[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]- including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]- follows.

#### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]- as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

There is currently limited data available for 1,2-propanediol, 3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]-. The Agency received three studies specifically testing 1,2-propanediol, 3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]-: acute oral toxicity, acute dermal toxicity, and an Ames assay. Those studies showed that 1,2-propanediol, 3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]- was non-toxic via acute oral and acute dermal exposures and was negative for mutagenicity. To assess the remaining potential toxicity of 1,2-propanediol, 3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]-, the Agency relied on data for a suitable cluster of structurally related linear short chain siloxane (Si-2 to Si-5) compounds. Based on the similar structures and physicochemical properties of these compounds to 1,2-propanediol, 3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]-, which primarily differ only in the number of siloxane units, the Agency has determined that the toxicological properties of these compounds is representative of the toxicity of 3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]-. The Agency has also determined that these data adequately address the physicochemical, mammalian

metabolism, mammalian toxicological, and environmental fate endpoints of 1,2-propanediol, 3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]-.

Oral repeat dose toxicity studies are available for structurally similar linear short chain siloxane chemicals, for durations ranging from 28 days up to one year in rats, rabbits, and dogs. The lowest NOAELs were in the 25 milligram/kilogram/day (mg/kg/day) range for two 28-day oral repeat dose rat studies and a 90-day dog study. LOAELs for these studies were based mainly on liver effects which were present in all of these studies.

Dermal repeated dose toxicity studies are available for two of the structurally similar linear short chain siloxane compounds. A 28-day dermal toxicity study in rats and rabbits showed no adverse effects up to limit dose of 1,000 mg/kg/day. The NOAEL was 1,000 mg/kg/day; the highest dose tested in both studies.

Inhalation repeated dose toxicity studies are available for three of the structurally similar linear short chain siloxane compounds. Both 28-day and 90-day rat inhalation studies are available as well as a one-year chronic inhalation study. The lowest inhalation NOAEL was 3.9 milligrams per Liter (mg/L) in a 90-day study, equivalent to a dose of greater than 1,000 mg/kg/day, a limit dose value.

A carcinogenicity study is available on one structurally-related short chain siloxane compound. An increase incidence of Leydig cell tumors (LCTs) in males was observed at all doses. However, due to the high background incidence of LCTs in Fischer 344 rats, this effect has been determined to not be treatment-related. Renal tubular adenomas and carcinomas were also observed in the study but are attributable to male rat specific alpha-2 $\mu$ -globulin mediated nephrotoxicity and therefore not relevant to cancer risk concerns in humans. Genotoxicity studies on 1,2-propanediol, 3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]- and structurally-related compounds were negative for genotoxic effects. A DEREK (structure-activity modeling) analysis was conducted and identified no structural alerts for possible carcinogenicity among the linear short chain siloxane compounds. Therefore, based on the lack of human-relevant carcinogenicity in the available study, and the results of the genotoxicity studies and DEREK analysis, 1,2-propanediol, 3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]- is not expected to be carcinogenic.

Reproductive and developmental toxicity studies with linear short chain siloxane compounds demonstrated no adverse effects at doses at or below limit dose levels. No evidence of immunotoxicity or neuro toxicity at doses below the limit dose was observed in the available studies for the structurally related linear short chain siloxane (Si-2 to Si-5) compounds at up to limit dose levels.

There are currently no publically-available metabolism studies for 1,2-propanediol, 3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]-, however, the expected mammalian metabolic pathways which may be involved in the degradation of 1,2-propanediol, 3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]- include a combination of ether hydrolysis followed by  $\beta$ -oxidation of the carbon chain followed by methyl oxidation of the silyl methyl groups. Methyl oxidation would result in the formation of a mixture of primary and alcohol metabolites. The more polar primary alcohol functionalities can both be conjugated and excreted directly or further oxidized to form a mixture of more polar carboxylic acid metabolites that are readily conjugated and excreted.

Specific information on the studies received and the nature of the adverse effects caused by 1,2-propanediol, 3-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]- as well as the NOAEL and the LOAEL from the toxicity studies can be found at <http://www.regulations.gov> in document, "1,2-Propanediol, 3-[3-[1,3,3,3-tetraamethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]-; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pre-harvest Pesticide Products Under 40 CFR 180.920" in docket ID number EPA-HQ-OPP-2014-0449.

#### B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each

toxicological study to determine the dose at which the NOAEL and the LOAEL are identified. Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk

assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl]propoxy]- used for human risk assessment is shown in Table 1 of this unit.

The 28-day studies in rats the NOAEL was 25 mg/kg/day with a LOAEL of 250 mg/kg/day based on based on increases in absolute liver weights, hepatocellular hypertrophy and protoporphyrin accumulation with associated bile duct proliferation and periportal chronic inflammation. A 90-day dog study had

a NOAEL of 24 mg/kg/day with a LOAEL of 77 mg/kg/day based on increased relative liver weight in females and lower relative testes weight in males with slight testicular atrophy or hypoplasia in males. A NOAEL of 25 mg/kg/day was selected for use as the endpoint for dietary exposure in this risk assessment. An additional uncertainty factor of 3X was applied for the use of shorter term study for a chronic risk assessment.

Dermal and inhalation exposure endpoints were not selected as there were no adverse effects observed up to limit dose levels in both rat and rabbit dermal and inhalation toxicity studies.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR 1,2-PROPANEDIOL, 3-[3-[1, 3, 3, 3-TETRAMETHYL-1-[(TRIMETHYLSILYL)OXY]-1-DISILOXYANYL] PROPOXY]- FOR USE IN HUMAN RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations) .....	An acute effect was not found in the database therefore an acute dietary assessment is not necessary.		
Chronic dietary (All populations) ....	NOAEL= 25 mg/kg/day ..... UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 3x	Chronic RfD = 0.08 mg/kg/day ..... cPAD = 0.08 mg/kg/day .....	28-Day oral toxicity study-rat LOAEL = 250 mg/kg/day based on protoporphyrin accumulation in the liver.
Incidental oral short-term (1 to 30 days).	NOAEL= 25 mg/kg/day ..... UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 3x	LOC for MOE = 300 .....	28-Day oral toxicity study-rat LOAEL = 250 mg/kg/day based on protoporphyrin accumulation in the liver.
Incidental oral intermediate-term (1 to 6 months).	NOAEL= 25 mg/kg/day ..... UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 3x	LOC for MOE = 300 .....	28-Day oral toxicity study-rat LOAEL = 250 mg/kg/day based on protoporphyrin accumulation in the liver.
Cancer (Oral, dermal, inhalation) ..	Not likely to be carcinogenic to humans based on the lack of increased incidence of tumor formation compared to controls in the 1-year carcinogenicity study, lack of mutagenicity, and no structural alerts for genotoxicity or carcinogenicity identified in a qualitative structure activity relationship (SAR) database, DEREK.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). UF<sub>S</sub> = use of a short-term study for long-term risk assessment.

C. Exposure Assessment

1. Dietary exposure from food and feed uses. In evaluating dietary exposure to 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl]propoxy]-, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl]propoxy]- in food as follows:

i. Acute Exposure. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide chemical, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies

for 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl]propoxy]-; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. Chronic exposure. The chronic dietary exposure assessment for this inert ingredient utilizes the Dietary Exposure Evaluation Model Food Commodity Intake Database (DEEM-FCID), Version 3.16, EPA, which includes food consumption information from the U.S. Department of Agriculture’s National Health and Nutrition Examination Survey, “What We Eat In America”, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. In the absence of actual residue data, the inert ingredient evaluation is based on a highly conservative model which

assumes that the residue level of the inert ingredient would be no higher than the highest established tolerance for an active ingredient on a given commodity. Implicit in this assumption is that there would be similar rates of degradation between the active and inert ingredient (if any) and that the concentration of inert ingredient in the scenarios leading to these highest of tolerances would be no higher than the concentration of the active ingredient. The model assumes 100 percent crop treated (PCT) for all crops and that every food eaten by a person each day has tolerance-level residues. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled “Alkyl Amines Polyalkoxylates (Cluster 4):

Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts,” (D361707, S. Piper, 2/25/09) and can be found at <http://www.regulations.gov> in docket ID number EPA-HQ-OPP-2008-0738.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl]propoxy]- does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

2. *Dietary exposure from drinking water*. For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl]propoxy]-, a conservative drinking water concentration value of 100 parts per billion (ppb) based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure*. The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Residential use patterns are possible for pesticide products containing 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl]propoxy]-. Residential exposure could occur via the dermal and inhalation routes of exposure. However, there are no concerns for dermal or inhalation exposure because no effects were seen in dermal or inhalation toxicity studies up to the limit dose. Incidental oral exposure for children is possible either by hand-to-mouth or object-to-mouth ingestion resulting from contact with treated surfaces.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

EPA has not found 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl]

propoxy]- to share a common mechanism of toxicity with any other substances, and 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl]propoxy]- does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl]propoxy]- does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s Web site at <http://www.epa.gov/pesticides/cumulative>.

#### D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. Although some adverse reproductive effects were observed in the inhalation developmental/reproductive toxicity studies, these effects were at dose levels far in excess of the clear NOAEL established in the oral reproductive and developmental screening study and the regulatory doses used in the risk assessment were selected to be protective of these effects.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 3x to account for the use of a subchronic study to derive a chronic reference dose. That decision is also based on the following findings:

i. Although only limited data on 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl]propoxy]- is available, the Agency has reliable data based on the structurally related linear short chain siloxane (Si-2 to Si-5) compounds to adequately characterize the toxicity and assess the

risk from dietary exposure to 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl]propoxy]-.

ii. There is no indication that 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl]propoxy]- is a neurotoxic chemical at doses below the limit dose and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. There is no indication that 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl]propoxy]- is an immunotoxic chemical and there is no need for an immunotoxicity study or additional UFs to account for immunotoxicity.

iv. As discussed in Unit IV.D.2., there is no need to retain the FQPA 10x to address any concern for potential increased susceptibility in infants and children from prenatal or postnatal exposure to 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl]propoxy]-.

v. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on a highly conservative model that assumes 100 percent crop treated (PCT) for all crops and that every food eaten by a person each day has residues of inert ingredient equivalent to the residue level of the highest established tolerance for an active ingredient on a given commodity. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl]propoxy]- in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl]propoxy]-.

#### E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate

PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- from food and water will utilize 88.3% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in this unit regarding residential use patterns, chronic residential exposure to residues of 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

1,2-Propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- may be used as an inert ingredient in pesticide products that would result in short-term residential exposure. Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Although short-term residential exposure is possible, there was no endpoint of concern identified in both dermal and inhalation toxicity studies. However the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures for children. EPA has concluded the combined short-term aggregated food, water, and residential exposures results in an aggregate MOE of 334 for children. Children's aggregate MOE combines average food and water exposure from the chronic dietary exposure with residential exposure associated with contact with treated lawns (hand-to-mouth + object-to-mouth). As the level of concern is for MOEs that are lower than 300, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic

exposure to food and water (considered to be a background exposure level).

1,2-Propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- may be used as an inert ingredient in pesticide products that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Although intermediate-term residential exposure is possible, there was no endpoint of concern identified in both dermal and inhalation toxicity. However the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures for children. EPA has concluded the combined intermediate-term aggregated food, water, and residential exposures results in an aggregate MOE of 342 for children. Children's aggregate MOE combines average food and water exposure from the chronic dietary exposure with residential exposure associated with contact with treated lawns (hand-to-mouth + object-to-mouth). As the level of concern is for MOEs that are lower than 300, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit IV.A., EPA does not expect 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- residues.

## V. Other Considerations

### A. Analytical Enforcement Methodology

Although EPA is establishing a limitation on the amount of 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- that may be used in pesticide formulations, an analytical enforcement methodology is not necessary for this exemption from the requirement of tolerance. The limitation will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide for sale or distribution for use on growing crops with concentrations of 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-

[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- exceeding 5% by weight of the formulation.

### B. Revisions to Petitioned-For Tolerances

Based upon an evaluation of the data included in the petition, EPA is establishing an exemption from the requirement of a tolerance for residues of 1,2-propanediol 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- when used in pesticide formulations as an inert ingredient (antifoaming agent), not to exceed 5% by weight of the formulation, instead of the 10% limit requested. The basis for this revision can be found at <http://www.regulations.gov> in document, "1,2-Propanediol,3-[3-[1,3,3,3-tetraamethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl]propoxy]-; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pre-harvest Pesticide Products Under 40 CFR 180.920" in docket ID number EPA-HQ-OPP-2014-0449.

## VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.920 for 1,2-propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- (CAS Reg. No. 70280-68-1) when used as an inert ingredient (antifoaming agent) in pesticide formulations applied to growing crops at a maximum concentration not to exceed 5% by weight in formulation.

## VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections

subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCFA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCFA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal

governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

**VIII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule 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**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 31, 2016.

**G. Jeffrey Herndon,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

■ 1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.920, add alphabetically the inert ingredient to the table to read as follows:

**§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

Inert ingredients	Limits	Uses
* * * * *		
1,2-Propanediol, 3-[3-[1, 3, 3, 3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxyanyl] propoxy]- (CAS Reg. No. 70280-68-1).	Not to exceed 5% by weight of pesticide formulation.	Antifoaming agent.
* * * * *		

[FR Doc. 2016-08282 Filed 4-11-16; 8:45 am]

**BILLING CODE 6560-50-P**

**GULF COAST ECOSYSTEM RESTORATION COUNCIL**

**40 CFR Part 1800**

[Docket Number: 104122016-1111-01]

**RESTORE Act Spill Impact Component Allocation**

**AGENCY:** Gulf Coast Ecosystem Restoration Council.

**ACTION:** Notice of effective date of final rule.

**SUMMARY:** This document confirms that on April 4, 2016, the United States District Court for the Eastern District of Louisiana entered a consent decree (Consent Decree) among the United States; the states of Alabama, Florida, Louisiana, Mississippi and Texas; and BP Exploration and Production Inc.

with respect to the civil penalty and natural resource damages in case number MDL No. 2179. The Gulf Coast Ecosystem Restoration Council (Council) regulation (Spill Impact Regulation) that implements the Spill Impact Component Allocation of the Resources and Ecosystems Sustainability, Tourist Opportunities, and Revived Economies of the Gulf Coast States Act of 2012 (RESTORE Act) is effective as of the date of publication of this document.

**DATES:** The Spill Impact Regulation is effective on April 12, 2016.

**FOR FURTHER INFORMATION CONTACT:** Will Spoon at (504) 239-9814.

**SUPPLEMENTARY INFORMATION:**

**Background**

On December 15, 2015, the Council published the Spill Impact Regulation in the **Federal Register** (80 FR 77580), to be effective on the date that the Council publishes this document in the **Federal Register** confirming that the

United States District Court for the Eastern District of Louisiana has entered the Consent Decree.

On April 4, 2016, the United States District Court for the Eastern District of Louisiana entered the Consent Decree. The Council confirms such entry by publication of this document, and the Spill Impact Regulation is therefore effective.

For more information on the Spill Impact Regulation, please see the final rule (80 FR 77580, December 15, 2015).

**Procedural Requirements**

*Regulatory Planning and Review (Executive Orders 12866 and 13563)*

As an independent Federal entity that is comprised, in part, of the Secretaries of the Departments of the Interior, Agriculture, Commerce and Homeland Security; the Secretary of the Army; and the Administrator of Environmental Protection Agency, the requirements of Executive Orders 12866 and 13563 do not apply to this document.

*Paperwork Reduction Act*

This document contains no collection of information requirements. Therefore the Paperwork Reduction Act does not apply to this document.

(Authority: 33 U.S.C. 1321(t).)

**Justin R. Ehrenwerth,**

*Executive Director, Gulf Coast Ecosystem Restoration Council.*

[FR Doc. 2016-08319 Filed 4-11-16; 8:45 am]

BILLING CODE 6560-58-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Part 447

[CMS-2328-F2]

RIN 0938-AS89

#### Medicaid Program; Deadline for Access Monitoring Review Plan Submissions

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule.

**SUMMARY:** In the November 2, 2015 *Federal Register*, we published a final rule with comment period entitled “Medicaid Program: Methods for Assuring Access to Covered Medicaid Services.” The final rule with comment period established that states must develop and submit to CMS an access monitoring review plan by July 1, 2016. This document revises the deadline for states’ access monitoring review plan submission to CMS until October 1, 2016.

**DATES:** *Effective Date:* These regulations are effective on April 8, 2016.

**FOR FURTHER INFORMATION CONTACT:** Jeremy Silanskis, (410) 786-1592.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the November 2, 2015 *Federal Register* (80 FR 67576), we published the “Medicaid Program: Methods for Assuring Access to Covered Medicaid Services” final rule with comment period that outlined a transparent data-driven process for states to document whether Medicaid payments are sufficient to enlist providers to assure beneficiary access to covered care and services consistent with section 1902(a)(30)(A) of the Social Security Act (the Act). This final rule with comment period included new § 447.203(b)(1) through (8) and revisions to

§ 447.203(b). These regulations established that states must develop and submit to CMS an access monitoring review plan by July 1, 2016 for the following service categories: Primary care services (including those provided by a physician, FQHC, clinic or dental care); physician specialist services (for example, cardiology, urology, radiology); behavioral health services (including mental health and substance use disorder); pre- and post-natal obstetric services, including labor and delivery; and home health services.

##### II. Discussion and Provisions of This Final Regulation

In the November 2, 2015 final rule with comment period, we solicited comments on § 447.203(b)(5). Specifically, we solicited comments on the scope of services required for ongoing review in the review plans, the elements of review required through the plans, whether we should allow exemptions to the rule based on state program characteristics (for example, high managed care enrollment), and the deadline for submission of the initial access monitoring review plan. We received many comments that were outside of the scope of issues on which we solicited comments. Several commenters raised concerns over CMS’s characterization in the regulatory preamble of the Supreme Court Decision: *Armstrong v. Exceptional Child Center, Inc.*, 135 S. Ct. 1378 (2015). Though we did not solicit comments on this issue, we agree with commenters that the decision is subject to judicial interpretation and we did not intend to imply an interpretation by the agency.

The following is a summary of the comments and our responses on § 447.203(b)(5).

*Comment:* We received many comments requesting that CMS not allow exemptions based on high managed care enrollment or other program features.

*Response:* While we continue to consider whether exemptions might be warranted in some circumstances, we believe that further experience with the access monitoring review system set forth in the final rule with comment period is necessary to determine the appropriate circumstances. The commenters did not offer consistent suggestions or supporting evidence to set a threshold that could exempt states, nor any suggestions for alternatives states might use to demonstrate compliance with section 1902(a)(30)(A) of the Act outside of the final rule with comment period requirements.

*Comment:* A number of commenters recommended that CMS expand the services that CMS requires states to review in access monitoring plans.

*Response:* Commenters that requested additional services did not provide sufficient data to compel us to modify the list of core services subject to the ongoing access reviews. The core services included in the final rule with comment period (that is, primary care services, physician specialist services, behavioral health services, pre- and post-natal obstetric services and home health services) were selected because they are frequently used services in Medicaid and access to these services indicates that an individual has primary sources of care, which may increase the likelihood of having their care needs met. We also note the final rule with comment period provides providers an opportunity and mechanism to bring access concerns to the attention of state Medicaid agencies and provide feedback on rate changes that may have a negative effect on access before states submit proposals to CMS.

*Comment:* Several commenters requested CMS change the due date by which states are required to develop and submit the initial Access Monitoring Review Plans. Commenters noted that state agency staff may have difficulty developing and submitting the initial review plans within the July 1, 2016 timeframe for first year reviews. These commenters offered several different dates as an alternative, including: January 1, 2017, July 1, 2017, and 6 months following the close of the state’s next legislative session. A number of other commenters requested CMS maintain the timelines established in the final rule.

*Response:* We established the July 1, 2016 deadline for developing and submitting the access monitoring review plans in the final rule with comment period after careful consideration of issues raised through comments on the notice of proposed rulemaking (76 FR 26342) and after weighing all of the policies discussed in the final rule. Since issuing the final rule with comment period, we have been working closely with states on developing the access monitoring review plans. States are actively engaged in developing plans and have raised significant concerns over fulfilling the requirements of the rule by the July 1, 2016 deadline. Several states have noted that additional time will allow them to develop more robust and proficient review plans, and leave them better prepared to analyze and monitor compliance with section 1902(a)(30)(A) of the Act. We agree with this assessment and believe that there

are programmatic benefits to revising the due date and making conforming changes to the deadline for submission in subsequent review periods.

*Revision to the Access Monitoring Review Plan Timeframe:* Based on concerns raised by commenters, in this final rule we are revising the deadline for submission effective date of the initial access monitoring review plan timeframe provision at § 447.203(b)(5) introductory text until October 1, 2016. A conforming change will also be made to the deadline for submission in subsequent review periods at § 447.203(b)(5)(i) to October 1.

### III. Waiver of Proposed Rulemaking and Delayed Effective Date

Under section 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rule in the **Federal Register** before the provisions of a rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. In addition, section 553(d) of the APA, and section 1871(e)(1)(B)(i) of the Act mandate a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the APA notice and comment, and delay in effective date requirements; similarly, sections 1871(b)(2)(C) and 1871(e)(1)(B)(ii) of the Act provide exceptions from the notice and comment, and delay in effective date requirements of the Act. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal notice and comment rulemaking procedures for good cause if the agency makes a finding that the notice and comment process is impracticable, unnecessary, or contrary to the public interest; and includes a statement of the finding and the reasons for it in the notice. In addition, both section 553(d)(3) of the APA and section 1871(e)(1)(B)(ii) of the Act allow the agency to avoid the 30-day delay in effective date where such delay is contrary to the public interest and the agency includes in the rule a statement of the finding and the reasons for it.

Because the deadlines for submission of access monitoring review plans are rules of procedure, the notice and comment requirements of 5 U.S.C. 553 do not apply to this delay of the submission date. *See* 5 U.S.C. 553(b)(3)(A). To the extent that section 553 applies in these circumstances

however, CMS finds that the action comes within the provision's good cause exceptions because obtaining additional public comment is impracticable, unnecessary, and contrary to the public interest. *See* 5 U.S.C. 553(b)(3)(B). Given the imminence of the submission date, and the need for states to plan and allocate resources in advance, seeking public comment and having a delayed effective date for this short delay in the deadline for submission of access monitoring review plans is impracticable. And, because we provided an opportunity for public comment on issues that included the submission deadlines, further opportunity is not necessary. Moreover, we believe that delay of the submission deadlines would further the public interest in orderly implementation of regulatory requirements, and in ensuring development of viable access monitoring review plans in light of assertions by commenters that compliance with the original submission deadlines might be infeasible or disruptive.

### IV. Collection of Information Requirements

The November 2, 2015 final rule with comment period stipulated that states must develop and submit (to CMS) their initial access monitoring review plan by July 1, 2016. We are now extending the submission deadline to October 1, 2016. Similarly, we are revising the deadline for subsequent review periods from July 1 to October 1. Otherwise, this final rule does not impose any new or revised information collection requirements or burden. The November 2, 2015, information collection requirements and burden are approved by OMB under control number 0938-1134 (CMS-10391).

### V. Regulatory Impact Statement

In the November 2, 2015 final rule with comment period, we discussed the impact of the access monitoring review plan requirements on states. We do not believe this delay of the deadline for submission of the access monitoring review plans will change any of the discussion in the impact statement of the November 2, 2015 final rule with comment period.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

### List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and

recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

### PART 447—PAYMENTS FOR SERVICES

■ 1. The authority citation for part 447 continues to read as follows:

**Authority:** Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

#### § 447.203 [Amended]

■ 2. Section 447.203 is amended by:

■ a. In paragraph (b)(5) introductory text, removing the date “July 1, 2016” and adding in its place the date “October 1, 2016”.

■ b. In paragraph (b)(5)(i), removing all instances of the date “July 1” and adding in their place the date “October 1”.

Dated: March 11, 2016.

**Andrew M. Slavitt,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

Dated: April 6, 2016.

**Sylvia M. Burwell,**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2016-08368 Filed 4-8-16; 4:15 pm]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### 50 CFR Part 20

[Docket No. FWS-HQ-MB-2015-0034; FF09M21200-167-FXMB1231099BPP0]

RIN 1018-BA70

### Migratory Bird Hunting; Final Frameworks for Migratory Bird Hunting Regulations

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Final rule; correction.

**SUMMARY:** We, the U.S. Fish and Wildlife Service, published a final rule in the **Federal Register** on March 28, 2016, that prescribes final frameworks from which States may select season dates, limits, and other options for the 2016-17 migratory bird hunting seasons. In that rule, we made an error in the daily bag limit for canvasbacks in Alaska. We intended to increase the daily bag limit for canvasbacks in Alaska, as we did for the rest of the United States, to 2 birds. We also

included an incorrect description for the Special Early Canada Goose Unit in South Dakota. With this document, we correct our errors.

**DATES:** This correction is effective April 12, 2016.

**FOR FURTHER INFORMATION CONTACT:** Ron W. Kokel, (703) 358-1714.

**SUPPLEMENTARY INFORMATION:** In a final rule that published in the **Federal Register** on March 28, 2016, at 81 FR 17302, the following corrections are made:

**Final Regulations Frameworks for 2016-17 Hunting Seasons on Certain Migratory Game Birds [Corrected]**

1. On page 17317, in the second column, under the heading “Alaska” and the subheading “Daily Bag and Possession Limits,” the third sentence under “Ducks:” is amended by removing the words “1 canvasback” and adding in their place the words “2 canvasbacks”.

2. On page 17330, in the first column, under the heading “South Dakota” and the subheading “Early Canada Goose Seasons,” remove the entire paragraph beginning with the words “Special Early Canada Goose Unit:” and add in its place the following paragraph: “Special Early Canada Goose Unit: The Counties of Campbell, Marshall, Roberts, Day, Clark, Codington, Grant, Hamlin, Deuel, Walworth; that portion of Perkins County west of State Highway 75 and south of State Highway 20; that portion of Dewey County north of Bureau of Indian Affairs Road 8, Bureau of Indian Affairs Road 9, and the section of U.S. Highway 212 east of the Bureau of Indian Affairs Road 8 junction; that portion of Potter County east of U.S. Highway 83; that portion of Sully County east of U.S. Highway 83; portions of Hyde, Buffalo, Brule, and Charles Mix counties north and east of a line beginning at the Hughes-Hyde County line on State Highway 34, east to Lees Boulevard, southeast to State Highway 34, east 7 miles to 350th Avenue, south to Interstate 90 on 350th Avenue, south and east on State Highway 50 to Geddes, east on 285th Street to U.S. Highway 281, and north on U.S. Highway 281 to the Charles Mix-Douglas County boundary; that portion of Bon Homme County north of State Highway 50; those portions of Yankton and Clay Counties north of a line beginning at the junction of State Highway 50 and 306th Street/County Highway 585 in Bon Homme County, east to U.S. Highway 81, then north on U.S. Highway 81 to 303rd Street, then east on 303rd Street to 444th Avenue, then south on 444th Avenue to 305th

Street, then east on 305th Street/Bluff Road to State Highway 19, then south to State Highway 50 and east to the Clay/Union County Line; McPherson, Edmunds, Kingsbury, Brookings, Lake, Moody, Miner, Faulk, Hand, Jerauld, Douglas, Hutchinson, Turner, Aurora, Beadle, Davison, Hanson, Sanborn, Spink, Brown, Harding, Butte, Lawrence, Meade, Oglala Lakota (formerly Shannon), Jackson, Mellette, Todd, Jones, Haakon, Corson, Ziebach, and McCook Counties; and those portions of Minnehaha and Lincoln counties outside of an area bounded by a line beginning at the junction of the South Dakota-Minnesota State line and Minnehaha County Highway 122 (254th Street) west to its junction with Minnehaha County Highway 149 (464th Avenue), south on Minnehaha County Highway 149 (464th Avenue) to Hartford, then south on Minnehaha County Highway 151 (463rd Avenue) to State Highway 42, east on State Highway 42 to State Highway 17, south on State Highway 17 to its junction with Lincoln County Highway 116 (Klondike Road), and east on Lincoln County Highway 116 (Klondike Road) to the South Dakota-Iowa State line, then north along the South Dakota-Iowa and South Dakota-Minnesota border to the junction of the South Dakota-Minnesota State line and Minnehaha County Highway 122 (254th Street).”

Dated: April 6, 2016.

**Tina A. Campbell,**

*Chief, Division of Policy, Performance, and Management Programs, U.S. Fish and Wildlife Service.*

[FR Doc. 2016-08326 Filed 4-11-16; 8:45 am]

**BILLING CODE 4310-55-P**

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 635**

[Docket No. 150121066-5717-02]

**RIN 0648-XE539**

**Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries**

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

**ACTION:** Temporary rule; closure of Angling category southern area trophy fishery.

**SUMMARY:** NMFS closes the southern area Angling category fishery for large medium and giant (“trophy”) (*i.e.*,

measuring 73 inches curved fork length or greater)) Atlantic bluefin tuna (BFT). This action is being taken to prevent any further overharvest of the Angling category southern area trophy BFT subquota.

**DATES:** Effective 11:30 p.m., local time, April 10, 2016, through December 31, 2016.

**FOR FURTHER INFORMATION CONTACT:** Sarah McLaughlin or Brad McHale, 978-281-9260.

**SUPPLEMENTARY INFORMATION:**

Regulations implemented under the authority of the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) governing the harvest of BFT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 635. Section 635.27 subdivides the U.S. BFT quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) among the various domestic fishing categories, per the allocations established in the 2006 Consolidated Atlantic Highly Migratory Species Fishery Management Plan (2006 Consolidated HMS FMP) (71 FR 58058, October 2, 2006), as amended by Amendment 7 to the 2006 Consolidated HMS FMP (Amendment 7) (79 FR 71510, December 2, 2014), and in accordance with implementing regulations.

NMFS is required, under § 635.28(a)(1), to file a closure notice with the Office of the Federal Register for publication when a BFT quota is reached or is projected to be reached. On and after the effective date and time of such notification, for the remainder of the fishing year or for a specified period as indicated in the notification, retaining, possessing, or landing BFT under that quota category is prohibited until the opening of the subsequent quota period or until such date as specified in the notice.

**Angling Category Large Medium and Giant Southern “Trophy” Fishery Closure**

The 2016 BFT fishing year, which is managed on a calendar-year basis and subject to an annual calendar-year quota, began January 1, 2016. The Angling category season opened January 1, 2016, and continues through December 31, 2016. The currently codified Angling category quota is 195.2 mt, of which 4.5 mt is allocated for the harvest of large medium and giant (trophy) BFT from the regulatory area by vessels fishing under the Angling



category quota, with 1.5 mt allocated for each of the following areas: North of 39°18' N. lat. (off Great Egg Inlet, NJ); south of 39°18' N. lat. and outside the Gulf of Mexico; and in the Gulf of Mexico. Trophy BFT measure 73 inches (185 cm) curved fork length or greater.

As of April 4, 2016, reported landings from the NMFS Automated Catch Reporting System and the North Carolina Tagging Program total approximately 1.6 mt. NMFS has determined that the codified Angling category southern area trophy BFT subquota has been reached and that a closure of the southern area trophy BFT fishery is warranted at this time.

Therefore, retaining, possessing, or landing large medium or giant BFT south of 39°18' N. lat. and outside the Gulf of Mexico by persons aboard vessels permitted in the HMS Angling category and the HMS Charter/Headboat category must cease at 11:30 p.m. local time on April 10, 2016. This closure will remain effective through December 31, 2016. This action is intended to prevent any further overharvest of the Angling category southern area trophy BFT subquota, and is taken consistent with the regulations at § 635.28(a)(1).

If needed, subsequent Angling category adjustments will be published in the **Federal Register**. Information regarding the Angling category fishery for Atlantic tunas, including daily retention limits for BFT measuring 27 inches (68.5 cm) to less than 73 inches and any further Angling category adjustments, is available at [hmspermits.noaa.gov](http://hmspermits.noaa.gov) or by calling (978) 281-9260.

HMS Angling and HMS Charter/Headboat category permit holders may catch and release (or tag and release) BFT of all sizes, subject to the requirements of the catch-and-release and tag-and-release programs at § 635.26. Anglers are also reminded that all BFT that are released must be handled in a manner that will maximize survival, and without removing the fish from the water, consistent with requirements at § 635.21(a)(1). For additional information on safe handling, see the "Careful Catch and Release" brochure available at [www.nmfs.noaa.gov/sfa/hms/](http://www.nmfs.noaa.gov/sfa/hms/).

#### Classification

The Assistant Administrator for NMFS (AA) finds that it is impracticable and contrary to the public interest to provide prior notice of, and an opportunity for public comment on, this action for the following reasons:

The regulations implementing the 2006 Consolidated HMS FMP, as

amended, provide for inseason retention limit adjustments and fishery closures to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. The closure of the southern area Angling category trophy fishery is necessary to prevent any further overharvest of the southern area trophy fishery subquota. NMFS provides notification of closures by publishing the notice in the **Federal Register**, emailing individuals who have subscribed to the Atlantic HMS News electronic newsletter, and updating the information posted on the Atlantic Tunas Information Line and on [hmspermits.noaa.gov](http://hmspermits.noaa.gov).

These fisheries are currently underway and delaying this action would be contrary to the public interest as it could result in excessive trophy BFT landings that may result in future potential quota reductions for the Angling category, depending on the magnitude of a potential Angling category overharvest. NMFS must close the southern area trophy BFT fishery before additional landings of these sizes of BFT accumulate. Therefore, the AA finds good cause under 5 U.S.C. 553(b)(B) to waive prior notice and the opportunity for public comment. For all of the above reasons, there is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness.

This action is being taken under 50 CFR 635.28(a)(1), and is exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: April 7, 2016.

**Emily H. Menashes,**

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

[FR Doc. 2016-08386 Filed 4-7-16; 4:15 pm]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 679

[Docket No. 150916863-6211-02]

RIN 0648-XE558

#### Fisheries of the Exclusive Economic Zone off Alaska; Exchange of Flatfish in the Bering Sea and Aleutian Islands Management Area

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

**ACTION:** Temporary rule; reallocation.

**SUMMARY:** NMFS is exchanging unused rock sole Community Development Quota (CDQ) for yellowfin sole CDQ acceptable biological catch (ABC) reserves in the Bering Sea and Aleutian Islands management area. This action is necessary to allow the 2016 total allowable catch of rock sole, and yellowfin sole in the Bering Sea and Aleutian Islands management area to be harvested.

**DATES:** Effective April 12, 2016, through December 31, 2016.

**FOR FURTHER INFORMATION CONTACT:** Steve Whitney, 907-586-7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the Bering Sea and Aleutian Islands management area (BSAI) according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2016 rock sole and yellowfin sole CDQ reserves specified in the BSAI are 6,110 mt, and 15,408 mt as established by the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016). The 2016 rock sole and yellowfin sole CDQ ABC reserves are 11,128 mt and 7,244 mt as established by the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016).

The Norton Sound Economic Development Corporation has requested that NMFS exchange 400 mt of rock sole CDQ reserves for 400 mt of yellowfin sole CDQ ABC reserves under § 679.31(d). Therefore, in accordance with § 679.31(d), NMFS exchanges 400 mt of rock sole CDQ reserves for 400 mt of yellowfin sole CDQ ABC reserves in the BSAI. This action also decreases and increases the TACs and CDQ ABC reserves by the corresponding amounts. Tables 11 and 13 of the final 2016 and 2017 harvest specifications for groundfish in the BSAI (81 FR 14773, March 18, 2016) are revised as follows:

TABLE 11—FINAL 2016 COMMUNITY DEVELOPMENT QUOTA (CDQ) RESERVES, INCIDENTAL CATCH AMOUNTS (ICAS), AND AMENDMENT 80 ALLOCATIONS OF THE ALEUTIAN ISLANDS PACIFIC OCEAN PERCH, AND BSAI FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE TACS

[Amounts are in metric tons]

Sector	Pacific Ocean perch			Flathead sole	Rock sole	Yellowfin sole
	Eastern Aleutian District	Central Aleutian District	Western Aleutian District	BSAI	BSAI	BSAI
TAC .....	7,900	7,000	9,000	21,000	56,700	144,400
CDQ .....	845	749	963	2,247	5,710	15,808
ICA .....	200	75	10	5,000	6,000	3,500
BSAI trawl limited access .....	685	618	161	0	0	14,979
Amendment 80 .....	6,169	5,558	7,866	13,753	44,990	110,113
Alaska Groundfish Cooperative .....	3,271	2,947	4,171	1,411	11,129	43,748
Alaska Seafood Cooperative .....	2,898	2,611	3,695	12,342	33,861	66,365

**Note:** Sector apportionments may not total precisely due to rounding.

TABLE 13—FINAL 2016 AND 2017 ABC SURPLUS, COMMUNITY DEVELOPMENT QUOTA (CDQ) ABC RESERVES, AND AMENDMENT 80 ABC RESERVES IN THE BSAI FOR FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE

[Amounts are in metric tons]

Sector	2016 Flathead sole	2016 Rock sole	2016 Yellowfin sole	2017 Flathead sole	2017 Rock sole	2017 Yellowfin sole
ABC .....	66,250	161,100	211,700	64,580	145,000	203,500
TAC .....	21,000	56,700	144,400	21,000	57,100	144,000
ABC surplus .....	45,250	104,400	67,300	43,580	87,900	59,500
ABC reserve .....	45,250	104,400	67,300	43,580	87,900	59,500
CDQ ABC reserve .....	4,842	11,528	6,844	4,663	9,405	6,367
Amendment 80 ABC reserve .....	40,408	92,872	60,456	38,917	78,495	53,134
Alaska Groundfish Cooperative for 2016 <sup>1</sup> .....	4,145	22,974	24,019	n/a	n/a	n/a
Alaska Seafood Cooperative for 2016 <sup>1</sup> .....	36,263	69,898	36,437	n/a	n/a	n/a

<sup>1</sup> The 2017 allocations for Amendment 80 species between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2016.

### Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the flatfish exchange by the

Norton Sound Economic Development Corporation in the BSAI. Since these fisheries are currently open, it is important to immediately inform the industry as to the revised allocations. Immediate notification is necessary to allow for the orderly conduct and efficient operation of this fishery, to allow the industry to plan for the fishing season, and to avoid potential disruption to the fishing fleet as well as processors. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of March 31, 2016.

The AA also finds good cause to waive the 30-day delay in the effective

date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: April 7, 2016.

**Emily H. Menashes,**  
Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2016-08419 Filed 4-11-16; 8:45 am]

**BILLING CODE 3510-22-P**

# Proposed Rules

Federal Register

Vol. 81, No. 70

Tuesday, April 12, 2016

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-2016-5462; Directorate Identifier 2015-NM-131-AD]

RIN 2120-AA64

#### Airworthiness Directives; Airbus Airplanes

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to adopt a new airworthiness directive (AD) for certain Airbus Model A330-200, -200 Freighter and -300 series airplanes, and Model A340-200 and -300 series airplanes. This proposed AD was prompted by reports of spurious terrain awareness warning system (TAWS) alerts during approach and takeoff for airplanes fitted with the terrain and traffic collision avoidance system with transponder (T3CAS) when the T3CAS is constantly powered "ON" for more than 149 hours. This proposed AD would require repetitive on-ground power cycle of the T3CAS. We are proposing this AD to prevent spurious TAWS alerts (Collision Prediction and Alerting (CPA), or missing legitimate CPA), which could increase flight crew workload during critical landing or takeoff phases, and possibly result in reduced control of the airplane.

**DATES:** We must receive comments on this proposed AD by May 27, 2016.

**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 NPRM, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email [airworthiness.A330-A340@airbus.com](mailto:airworthiness.A330-A340@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-2016-5462; 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:** Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-1138; fax 425-227-1149.

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2016-5462; Directorate Identifier 2015-NM-131-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 Union, has issued EASA AD 2015-0125, dated July 1, 2015, corrected on July 3, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for certain Airbus Model A330-200, -200 Freighter and -300 series airplanes, and Model A340-200 and -300 series airplanes. The MCAI states:

Cases were reported of spurious Terrain Awareness Warning System (TAWS) alerts during approach and take off, with aeroplane fitted with the Terrain and Traffic Collision Avoidance System with Transponder (T3CAS). Investigations on the unit were launched with the manufacturer of the system (ACSS). The results of the laboratory investigation confirmed that an internal frozen Global Positioning System position anomaly occurs when the T3CAS is constantly powered 'ON' for more than 149 hours. The origin for this defect was identified as a counter limitation related to a T3CAS internal software misbehaviour, not self-detected.

This condition, if not corrected, could lead to spurious TAWS alerts (Collision Prediction and Alerting (CPA), or missing legitimate CPA), which could increase flight crew workload during critical landing or take off phases, possibly resulting in reduced control of the aeroplane.

Prompted by these reports, Airbus issued Alert Operators Transmission (AOT) A34L003-13 to provide instructions to accomplish an on ground repetitive power cycle of the T3CAS before exceeding 120 hours of continuous power, and EASA issued AD 2014-0242 to require repetitive on ground power cycles of the T3CAS unit.

Since that [EASA] AD was issued, the AOT A34L003-13 revision 1 has been issued which extend[s] the applicability to A340 aeroplanes modified in-service in accordance with Airbus SB 34-4282 (T3CAS std 1.2 unit installation). It was also identified that [EASA] AD 2014-0242 does not refer to affected A330 in-service aeroplanes on which SB A330-34-3271 or SB A330-34-3286 or SB A330-34-3301 have been embodied.

For the reason described above, this [EASA] AD retains the same required actions as EASA AD 2014-0242, which is superseded, expands the Applicability of the [EASA] AD to include post SB A330-34-3271, post SB A330-34-3286 and post SB A330-34-3301 A330 aeroplanes, and post SB A340-34-4282 A340 aeroplanes.

\* \* \* \* \*

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-2016-5462.

#### Related Service Information Under 1 CFR Part 51

Airbus has issued AOT A34L003-13, Revision 1, dated May 26, 2015. The service information describes procedures for an on-ground power cycle of the T3CAS. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

#### FAA's Determination and Requirements of This Proposed AD

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

#### Costs of Compliance

We estimate that this proposed AD affects 3 airplanes of U.S. registry.

We also estimate that it would take about 1 work-hour per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour. Required parts would cost about \$0 per product. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be \$255, or \$85 per product.

#### Authority for This Rulemaking

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

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701:

General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

#### Regulatory Findings

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

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

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

#### List of Subjects in 14 CFR Part 39

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

#### The Proposed Amendment

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

#### PART 39—AIRWORTHINESS DIRECTIVES

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

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

##### § 39.13 [Amended]

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

**Airbus:** Docket No. FAA-2016-5462; Directorate Identifier 2015-NM-131-AD.

##### (a) Comments Due Date

We must receive comments by May 27, 2016.

##### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to the following Airbus airplanes, certificated in any category.

(1) Airbus Model A330-201, -202, -203, -223, -243, -223F, -243F, -301, -302, -303, -321, -322, -323, -341, -342, and -343 airplanes, all manufacturer serial numbers on which Airbus Modification 202097 (T3CAS standard 1.1) or Modification 202849 (T3CAS standard 1.2) has been embodied in production, or Airbus Service Bulletin A330-34-3271, Airbus Service Bulletin A330-34-3286, or Airbus Service Bulletin A330-34-3301 have been embodied in-service.

(2) Airbus Model A340-211, -212, -213, -311, -312, and -313 airplanes, all manufacturer serial numbers on which Airbus Service Bulletin A340-34-4282 (T3CAS standard 1.2) has been embodied in-service.

#### (d) Subject

Air Transport Association (ATA) of America Code 34, Navigation.

#### (e) Reason

This AD was prompted by reports of spurious terrain awareness warning system (TAWS) alerts during approach and take off for airplanes fitted with the terrain and traffic collision avoidance system with transponder (T3CAS) when the T3CAS is constantly powered "ON" for more than 149 hours. We are issuing this AD to prevent spurious TAWS alerts (Collision Prediction and Alerting (CPA), or missing legitimate CPA), which could increase flight crew workload during critical landing or take off phases, and possibly result in reduced control of the airplane.

#### (f) Compliance

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

#### (g) Ground Power Cycle

For Model A330 and A340 airplanes equipped with a T3CAS unit having a part number specified in paragraphs (g)(1) or (g)(2) of this AD: Within 30 days after the effective date of this AD, or within 120 hours of continuous power of the T3CAS after installation of the T3CAS, as specified in any applicable service information in paragraph (h) of this AD, whichever occurs later, do an on-ground power cycle of the T3CAS, in accordance with the instructions of Airbus Alert Operators Transmission (AOT) A34L003-13, Revision 1, dated May 26, 2015. Thereafter, repeat the on-ground power cycle of the T3CAS, at intervals not to exceed 120 hours of continuous power of the T3CAS.

(1) Affected T3CAS Units are those having part number (P/N) 9005000-10101, Software Standard 1.1.

(2) Affected T3CAS Units are those having P/N 9005000-10202, Software Standard 1.2.

#### (h) Service Information Used To Install Part Affected

Paragraphs (h)(1) through (h)(4) of this AD identify the service information that was used to install the T3CAS, as specified in paragraph (g) of this AD.

- (1) Airbus Service Bulletin A330-34-3271.
- (2) Airbus Service Bulletin A330-34-3286.
- (3) Airbus Service Bulletin A330-34-3301.
- (4) Airbus Service Bulletin A340-34-4282.

#### (i) Parts Installation Limitations

As of the effective date of this AD, installation on an airplane of a T3CAS unit having a part number specified in paragraph (g) of this AD is acceptable, provided that, following installation, the T3CAS unit is power cycled on a recurrent basis, as required by paragraph (g) of this AD.

#### (j) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Airbus AOT A34L003-13, dated November 25, 2013, which is not incorporated by reference in this AD.

#### (k) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, International Branch, ANM-116, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Branch, send it to ATTN: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone 425-227-1138; fax 425-227-1149. Information may be emailed to: [9-ANM-116-AMOC-REQUESTS@faa.gov](mailto: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.

#### (l) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2015-0125, dated July 1, 2015, corrected on July 3, 2015, 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 Docket No. FAA-2016-5462.

(2) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email [airworthiness.A330-A340@airbus.com](mailto:airworthiness.A330-A340@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 March 30, 2016.

#### Victor Wicklund,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016-08255 Filed 4-11-16; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2016-5460; Directorate Identifier 2015-NM-188-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 A330-200 Freighter, -200, and -300 series airplanes. This proposed AD was prompted by a report of a manufacturing defect that affects the durability of affected parts in the cargo and cabin compartment. This proposed AD would require an inspection of affected structural parts in the cargo and cabin compartments to determine if proper heat-treatment has been done, and replacement if necessary. We are proposing this AD to prevent crack initiation and propagation, which could result in reduced structural integrity of the fuselage.

**DATES:** We must receive comments on this proposed AD by May 27, 2016.

**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 NPRM, contact Airbus SAS, Airworthiness Office—EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone: +33 5 61 93 36 96; fax: +33 5 61 93 45 80; email: [airworthiness.A330-A340@airbus.com](mailto:airworthiness.A330-A340@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-2016-5460; 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:** Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM-116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; telephone: 425-227-1138; fax: 425-227-1149.

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2016-5460; Directorate Identifier 2015-NM-188-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 Union, has issued European Airworthiness Directive 2015–0212, dated November 4, 2015, to correct an unsafe condition for all Airbus Model A330–200 Freighter, –200, and –300 series airplanes. The MCAI states:

Airbus quality controls identified that several structural parts, intended for cargo or cabin compartment installation, were manufactured from improperly heat-treated materials. Subsequent review identified that some of those parts were installed on airplanes manufactured between November 2011 and February 2013. From February 2013, Airbus implemented measures into manufacturing processes to ensure detection and to prevent installation of such non-conforming parts.

A detailed safety assessment was accomplished to identify the possible impact of affected parts on the airplane structure. The result of this structural analysis demonstrated the capability of the affected structure to sustain static limit loads, but failed to confirm that the affected structures met the certified fatigue life.

This condition, if not detected and corrected, could lead to crack initiation and propagation, possibly resulting in reduced structural integrity of the fuselage.

To address this potentially unsafe condition, Airbus issued [Mandatory] Service Bulletin (SB) SB A330–53–3227 and SB A330–53–3228 to provide inspection instructions for affected cargo and cabin structural parts respectively.

For the reasons described above, this [EASA] AD requires a one-time Special Detailed Inspection (SDI) [eddy current inspection] to measure the electrical conductivity of affected structural parts, to identify the presence or absence of heat treatment, and, depending on findings, corrective action [replacement].

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–2016–5460.

#### **Related Service Information Under 14 CFR Part 51**

Airbus has issued the following service information:

- Airbus Mandatory Service Bulletin A330–53–3227, dated August 18, 2015. The service information describes procedures to inspect affected structural parts in the cargo compartment to determine if proper heat-treatment has been done, and replacement of parts; and
- Airbus Mandatory Service Bulletin A330–53–3228, dated August 18, 2015. The service information describes procedures to inspect affected structural parts in the cabin compartment to determine if proper heat-treatment has been done, and replacement of parts.

This service information is reasonably available because the interested parties

have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

#### **FAA’s Determination and Requirements of This Proposed AD**

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

#### **Differences Between This Proposed AD and the Service Information**

Figure A–GFAAA, Sheet 01, “Inspection Flowchart,” of Airbus Mandatory Service Bulletin A330–53–3227, dated August 18, 2015; and Figure A–GFAAA, Sheet 01, “Inspection Flowchart” of Airbus Mandatory Service Bulletin A330–53–3228, dated August 18, 2015, note that if any other measured (conductivity) value is found, to check the non-destructive test (NDT) tool and perform a new measurement; and if that measured value is confirmed, contact Airbus for further instructions. This proposed AD would require that if a measured value is confirmed that is outside the measurements specified in the service information, a repair must be done using a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA; or EASA; or Airbus’s EASA Design Organization Approval (DOA).

#### **Costs of Compliance**

We estimate that this proposed AD affects 20 airplanes of U.S. registry.

We also estimate that it will take about 11 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be \$18,700, or \$935 per product.

In addition, we estimate that any necessary follow-on actions would take about 45 work-hours for a cost of \$3,825 per product. We have received no definitive data that would enable us to provide cost of the parts for the on-condition actions specified in this proposed AD. We have no way of determining the number of aircraft that might need this action.

According to the manufacturer, some of the costs of this proposed AD may be

covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

#### **Authority for This Rulemaking**

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

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

#### **Regulatory Findings**

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

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

1. Is not a “significant regulatory action” under Executive Order 12866;
2. Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

#### **List of Subjects in 14 CFR Part 39**

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

#### **The Proposed Amendment**

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

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

### § 39.13 [Amended]

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

**Airbus:** Docket No. FAA–2016–5460; Directorate Identifier 2015–NM–188–AD.

#### (a) Comments Due Date

We must receive comments by May 27, 2016.

#### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to Airbus Model A330–223F and –243F airplanes; A330–201, –202, –203, –223, and –243 airplanes; A330–301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes, certificated in any category, manufacturer serial numbers 1175, 1180, 1287 through 1475 inclusive, 1478, 1480, 1483, and 1506.

#### (d) Subject

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

#### (e) Reason

This AD was prompted by a report of a manufacturing defect (*i.e.* improperly heat-treated materials) that affects the durability of affected parts in the cargo and cabin compartment. We are issuing this AD to prevent crack initiation and propagation, which could result in reduced structural integrity of the fuselage.

#### (f) Compliance

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

#### (g) Inspection of Affected Structure in the Cargo Compartment

Within 72 months since first flight of the airplane, do an eddy current inspection (*i.e.*, conductivity measurement) of affected structural parts in the cargo compartment to determine if proper heat treatment has been done as identified in, and in accordance with, the Accomplishment Instructions of Airbus Service Bulletin A330–53–3227, dated August 18, 2015.

#### (h) Replacement of Non-Conforming Parts in the Cargo Compartment

If, during the inspection required by paragraph (g) of this AD, an affected structural part in the cargo compartment is identified to have a measured value greater than 26 megasiemens per meter (MS/m) or greater than 44.8% International Annealed Copper Standard (IACS), before further flight, replace the affected structural part with a serviceable part, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–53–3227, dated August 18, 2015.

#### (i) Repair of Non-Conforming Parts in the Cargo Compartment

If, during the inspection required by paragraph (g) of this AD, an affected structural part in the cargo compartment is identified to have a measured value other than those specified in Figure A–GFAAA, Sheet 01, “Inspection Flowchart,” of Airbus Mandatory Service Bulletin A320–53–3227, dated August 18, 2015, before further flight, repair 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).

#### (j) Inspection of Affected Structure in the Cabin Compartment

Within 72 months since first flight of the airplane, do an eddy current inspection of affected structural parts in the cargo compartment to determine if proper heat treatment has been done as identified in, and in accordance with, the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–53–3228, dated August 18, 2015.

#### (k) Replacement of Non-Conforming Parts in the Cabin Compartment

If, during the inspection required by paragraph (j) of this AD, an affected structural part in the cabin compartment is identified to have a measured value greater than 26 MS/m or greater than 44.8% IACS, before further flight, replace the affected structural part with a serviceable part, in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A330–53–3228, dated August 18, 2015.

#### (l) Repair of Non-Conforming Parts in the Cargo Compartment

If, during the inspection required by paragraph (j) of this AD, an affected structural part in the cargo compartment is identified to have a measured value other than those specified in Figure A–GFAAA, Sheet 01, “Inspection Flowchart,” of Airbus Service Bulletin A320–53–3228, dated August 18, 2015, before further flight, repair 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).

#### (m) 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: Vladimir Ulyanov, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind

Avenue SW., Renton, WA 98057–3356; telephone: 425–227–1138; 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.

(3) *Required for Compliance (RC):* If any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator’s maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

#### (n) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2015–0212, dated November 4, 2015, for related information. You may examine the MCAI on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2016–5460.

(2) For service information identified in this AD, contact Airbus SAS, Airworthiness Office–EAL, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone: +33 5 61 93 36 96; fax: +33 5 61 93 45 80; email: [airworthiness.A330-A340@airbus.com](mailto:airworthiness.A330-A340@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 March 30, 2016.

#### Victor Wicklund,

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2016–08253 Filed 4–11–16; 8:45 am]

**BILLING CODE 4910–13–P**

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2016-5578; Directorate Identifier 2016-CE-005-AD]

RIN 2120-AA64

**Airworthiness Directives; Pacific Aerospace Limited Airplanes****AGENCY:** Federal Aviation Administration (FAA), Department of Transportation (DOT).**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to adopt a new airworthiness directive (AD) for certain Pacific Aerospace Limited Model 750XL (type certificate previously held by Pacific Aerospace Corporation Ltd.) airplanes that would supersede AD 2006-13-05. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as some critical rivets on the wing not being fully age-hardened and being installed in specific locations where reduction in rivet strength reduces wing strength. We are issuing this proposed AD to require actions to address the unsafe condition on these products.

**DATES:** We must receive comments on this proposed AD by May 27, 2016.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* (202) 493-2251.
- *Mail:* U.S. Department of

Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Pacific Aerospace Limited, Airport Road, Hamilton, Private Bag 3027, Hamilton 3240, New Zealand; telephone: +64 7 843 6144; facsimile: +64 7 843 6134; email: [pacific@aerospace.co.nz](mailto:pacific@aerospace.co.nz); Internet: [www.aerospace.co.nz](http://www.aerospace.co.nz). You may review copies of the referenced

service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

**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-2016-5578; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

**FOR FURTHER INFORMATION CONTACT:** Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4123; fax: (816) 329-4090; email: [karl.schletzbaum@faa.gov](mailto:karl.schletzbaum@faa.gov).

**SUPPLEMENTARY INFORMATION:****Comments Invited**

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2016-5578; Directorate Identifier 2016-CE-005-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

**Discussion**

On June 12, 2006, we issued AD 2006-13-05, Amendment 39-14658 (71 FR 35509, June 21, 2006) ("AD 2006-13-05"). That AD required actions intended to address an unsafe condition on certain Pacific Aerospace Corporation Ltd. Model 750XL airplanes and was based on mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country.

Since we issued AD 2006-13-05, additional airplanes have been identified that need to be added to the applicability of the AD.

The Civil Aviation Authority (CAA), which is the aviation authority for New Zealand, has issued AD No. DCA/750XL/7B, dated February 25, 2016 (referred to after this as "the MCAI"), to correct an unsafe condition for the specified products. The MCAI states:

DCA/750XL/7B revised to introduce PACSB/XL/018 issue 4, dated 20 January 2016, which reduces the applicability to S/N 101 through to 131 with no change to the requirements. Aircraft with S/N 132 onwards have been modified in accordance with PACSB/XL/018 at manufacture, which is a terminating action for the requirements of this AD.

This proposed AD would require you to remove rivets that have not been fully age hardened and replace them with bolts, washers, and nuts in specific locations where reduction in rivet strength affects overall structural capability. The proposed AD would retain the airplane weight AFM limitations until the rivets are replaced with the bolts, washers, and nuts. You may examine the MCAI on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-5578.

**Related Service Information Under 14 CFR Part 51**

Pacific Aerospace Limited has issued Service Bulletin PACSB/XL/018, Issue 4, dated January 20, 2016. The service bulletin describes procedures for removing rivets (part number (P/N) MS20470 DD6) and installing bolts (P/N NAS 6203-7X or NAS 6203-6X), washers (P/N AN960-10), and nuts (P/N MS21044N3) in place of the rivets to restore airplane to full take-off weight of 7,500 pounds. The service bulletin is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this NPRM.

**FAA's Determination and Requirements of the 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 this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information and determined the unsafe condition exists and is likely to exist or



develop on other products of the same type design.

### Costs of Compliance

We estimate that this proposed AD will affect 9 products of U.S. registry. We also estimate that it would take about 32 work-hours per product to comply with the replacement requirements of this proposed AD. The average labor rate is \$85 per work-hour. Required parts would cost about \$519 per product.

Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be \$29,151, or \$3,239 per product.

AD 2006–13–05 affected 8 of the 9 U.S. registered airplanes reflected in the above cost information. This proposed AD would only increase the cost already required by AD 2006–13–05 by one additional airplane. The FAA has a report that the additional airplane is already in compliance, thus the proposed AD would impose no additional cost impact on U.S. operators.

### Authority for This Rulemaking

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

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

### Regulatory Findings

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

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

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

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

(3) Will not affect intrastate aviation in Alaska, and

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

### List of Subjects in 14 CFR Part 39

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

### The Proposed Amendment

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

### PART 39—AIRWORTHINESS DIRECTIVES

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

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

#### § 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Amendment 39–14658 (71 FR 35509, June 21, 2006), and adding the following new AD:

**Pacific Aerospace Limited:** Docket No. FAA–2016–5578; Directorate Identifier 2016–CE–005–AD.

#### (a) Comments Due Date

We must receive comments by May 27, 2016.

#### (b) Affected ADs

This AD replaces AD 2006–13–05, Amendment 39–14658 (71 FR 35509, June 21, 2006) ("AD 2006–13–05").

#### (c) Applicability

This AD applies to the following Pacific Aerospace Limited Model 750XL airplanes (type certificate previously held by Pacific Aerospace Corporation Ltd.), that are certificated in any category.

(1) *Airplanes previously affected by AD 2006–13–05:* Serial numbers 101, 102, 104 through 120, and 125.

(2) *Airplanes new to this AD:* Serial numbers 103, 121, 122, 123, 124, and 126 to 131.

#### (d) Subject

Air Transport Association of America (ATA) Code 57: Wings.

#### (e) Reason

This AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as some critical rivets on the wing not being fully age-

hardened and being installed in specific locations where reduction in rivet strength reduces wing strength. We are issuing this AD to add airplanes to the Applicability section, paragraph (c) of this AD, and to ensure wing ultimate load requirements are met. If wing ultimate load requirements are not met, wing failure could result with consequent loss of control.

### (f) Actions and Compliance

Unless already done, do the following actions:

(1) Insert the following information into the Limitations section of the airplane flight manual (AFM) at the compliance time specified in paragraphs (f)(1)(i) and (f)(1)(ii) of this AD. You may do this by inserting a copy of this AD into the Limitations section of the AFM: "The maximum takeoff weight is reduced from 7,500 pounds to 7,125 pounds." The owner/operator holding at least a private pilot certificate as authorized by section 43.7 of the Federal Aviation Regulations (14 CFR 43.7) may do the flight manual changes requirement of this AD. Make an entry in the aircraft records showing compliance with this portion of the AD following section 43.9 of the Federal Aviation Regulations (14 CFR 43.9).

(i) *For airplanes previously affected by AD 2006–13–05:* Before further flight after January 16, 2006 (the effective date retained from AD 2005–26–53, Amendment 39–14451 (71 FR 2453, January 17, 2006), which was replaced by AD 2006–13–05).

(ii) *For airplanes new to this AD:* Before further flight after the effective date of this AD.

(2) Remove rivets, part number (P/N) MS20470 DD6, on the main spar web and replace with bolts, P/N NAS 6203–6X or –7X, as indicated for the position, assembled with washers, P/N AN960–10, and nut, P/N MS21044N3, at the compliance time specified in paragraphs (f)(2)(i) and (f)(2)(ii) of this AD.

(i) *For airplanes previously affected by AD 2006–13–05:* Within the next 100 hours time-in-service (TIS) after July 31, 2006 (the effective date retained from AD 2006–13–05). Do the removal and replacement actions following Pacific Aerospace Corporation Ltd. Service Bulletin PACSB/XL/018, Issue 3, dated December 23, 2005, and amended January 16, 2006.

(ii) *For airplanes new to this AD:* Within the next 100 hours TIS after the effective date of this AD or within the next 12 months after the effective date of this AD, whichever occurs first. Do the removal and replacement actions following Pacific Aerospace Limited Service Bulletin PACSB/XL/018, Issue 4, dated January 20, 2016.

(3) *For all affected airplanes:* Before further flight after doing the action required in paragraph (f)(2) of this AD, remove the restrictive information from the Limitations section of the AFM that you were required to insert in paragraph (f)(1) of this AD. The owner/operator holding at least a private pilot certificate as authorized by section 43.7 of the Federal Aviation Regulations (14 CFR 43.7) may do the flight manual changes requirement of this AD.

**(g) Other FAA AD Provisions**

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4123; fax: (816) 329-4090; email: [karl.schletzbaum@faa.gov](mailto:karl.schletzbaum@faa.gov). Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

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

**(h) Related Information**

Refer to MCAI Civil Aviation Authority (CAA) AD No. DCA/750XL/7B, dated February 25, 2016, for related information. You may examine the MCAI on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-5578. For service information related to this AD, contact Pacific Aerospace Limited, Airport Road, Hamilton, Private Bag 3027, Hamilton 3240, New Zealand; telephone: +64 7 843 6144; facsimile: +64 7 843 6134; email: [pacific@aerospace.co.nz](mailto:pacific@aerospace.co.nz); Internet: [www.aerospace.co.nz](http://www.aerospace.co.nz). You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

Issued in Kansas City, Missouri, on April 4, 2016.

**Pat Mullen,**

*Acting Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2016-08261 Filed 4-11-16; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2016-5459; Directorate Identifier 2015-NM-148-AD]

RIN 2120-AA64

**Airworthiness Directives; Bombardier, Inc. Airplanes**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to adopt a new airworthiness directive (AD) for certain Bombardier, Inc. Model BD-700-1A10 and BD-700-1A11 airplanes. This proposed AD was prompted by a design review, which found that the burst pressure of the flexible hose used to vent oxygen from the high-pressure relief valve of the oxygen cylinder overboard is lower than the opening pressure of the high-pressure relief valve. This pressure difference could cause the flexible hose to burst before it is able to vent excess oxygen overboard. This proposed AD would require replacement of flexible relief hoses for the crew oxygen bottles with new metal design relief hoses. We are proposing this AD to prevent the accumulation of excess oxygen in an enclosed space, which could, if near a source of ignition, cause an uncontrolled oxygen-fed fire.

**DATES:** We must receive comments on this proposed AD by May 27, 2016.

**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 NPRM, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514-855-5000; fax 514-855-7401; email [thd.crj@aero.bombardier.com](mailto:thd.crj@aero.bombardier.com); Internet <http://www.bombardier.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-2016-5459; 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:**

Fabio Buttitta, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE-171, FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516-228-7303; fax 516-794-5531.

**SUPPLEMENTARY INFORMATION:****Comments Invited**

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2016-5459; Directorate Identifier 2015-NM-148-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**

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF-2015-25, dated September 10, 2015 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for certain Bombardier, Inc. Model BD-700-1A10 and BD-700-1A11 airplanes. The MCAI states:

A design review found that the burst pressure of the flexible hose used to vent oxygen from the high-pressure relief valve of the oxygen cylinder overboard is lower than the opening pressure of the high-pressure relief valve. This could cause the flexible hose to burst before it is able to vent the excess oxygen overboard. If an ignition source is present, the accumulation of oxygen in an enclosed space may result in an uncontrolled oxygen-fed fire.

This [Canadian] AD mandates the replacement of the oxygen [flexible] hose assembly with a new design oxygen [metal] hose assembly.

You may examine the MCAI in the AD docket on the Internet at <http://www.regulations.gov>

[www.regulations.gov](http://www.regulations.gov) by searching for and locating Docket No. FAA–2016–5459.

### Related Service Information Under 1 CFR Part 51

Bombardier, Inc. has issued the following service information:

- Service Bulletin 700–35–013, Revision 01, dated July 22, 2015;
- Service Bulletin 700–35–5001, Revision 01, dated July 22, 2015;
- Service Bulletin 700–35–6001, Revision 01, dated July 22, 2015;
- Service Bulletin 700–1A11–35–012, Revision 01, dated July 22, 2015.

The service information describes procedures to replace the flexible oxygen hoses with metal hoses. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

### FAA's Determination and Requirements of This Proposed AD

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

### Costs of Compliance

We estimate that this proposed AD affects 73 airplanes of U.S. registry.

We also estimate that it will take about 3 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour. Required parts would cost about \$14,483 per product. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be \$1,075,874, or \$14,738 per product.

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

### Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of

the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

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

### Regulatory Findings

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

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

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

### List of Subjects in 14 CFR Part 39

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

### The Proposed Amendment

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

### PART 39—AIRWORTHINESS DIRECTIVES

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

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

#### § 39.13 [Amended]

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

**Bombardier, Inc.:** Docket No. FAA–2016–5459; Directorate Identifier 2015–NM–148–AD.

#### (a) Comments Due Date

We must receive comments by May 27, 2016.

#### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to Bombardier, Inc. Model BD–700–1A10 and BD–700–1A11 airplanes, certificated in any category, having serial numbers (S/Ns) 9002 through 9704 inclusive and 9998.

#### (d) Subject

Air Transport Association (ATA) of America Code 35, Oxygen.

#### (e) Reason

This AD was prompted by a design review, which found that the burst pressure of the flexible hose used to vent oxygen from the high-pressure relief valve of the oxygen cylinder overboard is lower than the opening pressure of the high-pressure relief valve. This pressure difference could cause the flexible hose to burst before it is able to vent excess oxygen overboard. We are issuing this AD to prevent the accumulation of excess oxygen in an enclosed space, which could, if near a source of ignition, cause an uncontrolled oxygen-fed fire.

#### (f) Compliance

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

#### (g) Modification

Within 2,500 flight hours or 42 months, whichever occurs first, after the effective date of this AD, incorporate Bombardier Modsum R700T400542 by replacing the oxygen flexible relief hoses for the crew oxygen bottles with new metal design hoses, in accordance with the Accomplishment Instructions of the applicable service information specified in paragraphs (g)(1) through (g)(4) of this AD. Airplanes with serial numbers listed in table 1 of paragraph 1, "Planning information," of the service information specified in paragraphs (g)(2) and (g)(4) of this AD have incorporated Modsum R700T400542 and meet the requirements of this paragraph.

(1) For Model BD–700–1A10 airplanes having S/Ns 9002 through 9312 inclusive, 9314 through 9380 inclusive, and 9384 through 9429 inclusive: Bombardier Service Bulletin 700–35–013, Revision 01, dated July 22, 2015.

(2) For Model BD–700–1A10 airplanes having S/Ns 9313, 9381, and 9432 through 9704 inclusive: Bombardier Service Bulletin 700–35–6001, Revision 01, dated July 22, 2015.

(3) For Model BD–700–1A11 airplanes having S/Ns 9127 through 9383 inclusive, 9389 through 9400 inclusive, 9404 through 9431 inclusive, and 9998: Bombardier Service Bulletin 700–1A11–35–012, Revision 01, dated July 22, 2015.

(4) For Model BD–700–1A11 airplanes having S/Ns 9386, 9401, and 9445 through

9702 inclusive; Bombardier Service Bulletin 700–35–5001, Revision 01, dated July 22, 2015.

#### (h) Parts Installation Prohibition

As of the effective date of this AD, no person may install oxygen hoses in the low pressure/high pressure discharge system with part numbers listed in the “Used Part No.” column of Section 3.A, “Kit,” of the applicable service information specified in paragraphs (g)(1) through (g)(4) of this AD.

#### (i) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using the applicable service information identified in paragraphs (i)(1) through (i)(4) of this AD, which are not incorporated by reference in this AD.

- (1) Bombardier Service Bulletin 700–35–013, dated February 20, 2015;
- (2) Bombardier Service Bulletin 700–35–5001, dated February 20, 2015;
- (3) Bombardier Service Bulletin 700–35–6001, dated February 20, 2015; and
- (4) Bombardier Service Bulletin 700–1A11–35–012, dated February 20, 2015.

#### (j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs)*: The Manager, New York Aircraft Certification Office (ACO), ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *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, New York ACO, ANE–170, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.’s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

#### (k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian Airworthiness Directive CF–2015–25, dated September 10, 2015, 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 Docket No. FAA–2016–5459.

(2) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9,

Canada; telephone 514–855–5000; fax 514–855–7401; email [thd.crj@aero.bombardier.com](mailto:thd.crj@aero.bombardier.com); Internet <http://www.bombardier.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 March 30, 2016.

**Victor Wicklund,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2016–08270 Filed 4–11–16; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

**[Docket No. FAA–2015–5807; Directorate Identifier 2015–SW–063–AD]**

**RIN 2120–AA64**

#### **Airworthiness Directives; Airbus Helicopters**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to adopt a new airworthiness directive (AD) for Airbus Helicopters Model AS355NP helicopters with certain fire extinguishing systems. This proposed AD would require removing and installing the fire extinguishing system so that each squib on the engine compartment fire extinguisher is controlled by a matching control button. This proposed AD is prompted by the discovery that the left-hand discharge system of the fire extinguishing system was incorrectly connected to the right-hand engine compartment and the right-hand discharge system was incorrectly connected to the left-hand engine compartment. The proposed actions would correct the connections and would prevent the fire extinguishing system discharging to the wrong engine compartment, failure of the fire extinguishing system to control a fire, and subsequent loss of control of the helicopter.

**DATES:** We must receive comments on this proposed AD by June 13, 2016.

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

- *Federal eRulemaking Docket*: Go to <http://www.regulations.gov>. Follow the online instructions for sending your comments electronically.

- *Fax*: 202–493–2251.
- *Mail*: Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

- *Hand Delivery*: Deliver to the “Mail” address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

#### **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–2015–5807; or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the European Aviation Safety Agency (EASA AD), the economic 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 service information identified in this proposed rule, contact Airbus Helicopters, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at <http://www.airbushelicopters.com/techpub>.

You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177.

#### **FOR FURTHER INFORMATION CONTACT:**

George Schwab, Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 10101 Hillwood Pkwy, Fort Worth, TX 76177; telephone (817) 222–5110; email [george.schwab@faa.gov](mailto:george.schwab@faa.gov).

#### **SUPPLEMENTARY INFORMATION:**

#### **Comments Invited**

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

### Discussion

EASA, which is the Technical Agent for the Member States of the European Union, issued EASA Emergency AD No. 2011-0192-E, dated October 4, 2011, to correct an unsafe condition for Eurocopter (now Airbus Helicopters) Model AS355NP helicopters equipped with an Arrius 1A1 engine fire extinguishing system through production modification OP-3931. EASA advises that during an inspection of the engine fire extinguishing system on an AS355NP helicopter, the left hand (LH) fire extinguisher discharge system was found connected to the right hand (RH) engine compartment and the RH discharge system was connected to the LH engine compartment. An investigation showed that this erroneous installation was inherent in Eurocopter production modification OP-3931. According to EASA, this condition, if not detected and corrected, could lead to the discharge of the fire extinguisher in the wrong engine compartment in the event of a fire. Pending the development of a modified extinguishing system, EASA Emergency AD No. 2011-0192-E required installing a placard warning the flight crew of the erroneous installation until the squibs on each fire extinguisher are exchanged.

After EASA issued Emergency AD No. 2011-0192-E, Airbus Helicopters developed a permanent modification of the discharge system to reconfigure the position of the squibs on each fire extinguisher to line up with the control buttons. EASA subsequently issued superseding EASA AD No. 2015-0181, dated August 31, 2015, to retain the requirements of its previous Emergency AD and require the modification of the engine fire extinguishing discharge system within 12 months.

### FAA's Determination

These helicopters have been approved by the aviation authority of France and are approved for operation in the United States. Pursuant to our bilateral agreement with France, EASA, its technical representative, has notified us

of the unsafe condition described in its AD. We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition is likely to exist or develop on other products of the same type design.

### Related Service Information Under 1 CFR Part 51

We reviewed Airbus Helicopters Alert Service Bulletin No. AS355-26.00.10, Revision 0, dated July 2, 2015 (ASB AS355-26.00.10). ASB AS355-26.00.10 provides procedures for removing the fire extinguishing system and re-installing it in a configuration where the squibs match the positioning of the fire extinguisher discharge heads. ASB AS355-26.00.10 also specifies removing any previously-affixed placard on the instrument panel and installing new discharge system pipes. Helicopters with modification 07-3990 installed have already complied with ASB AS355-26.00.10.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

### Other Related Service Information

We also reviewed Eurocopter Emergency Alert Service Bulletin No. 26.00.09, Revision 0, dated September 15, 2011 (EASB 26.00.09), issued prior to the permanent modification developed by Airbus Helicopters. EASB 26.00.09 provided procedures for interchanging the squibs on each fire extinguisher. Until this was accomplished, EASB 26.00.09 specified affixing a label on the instrument panel to make the flight crew aware of the crossed connection.

### Proposed AD Requirements

This proposed AD would require within 600 hours time-in-service or at the next annual inspection, whichever occurs first, removing and correctly installing the fire extinguishing system, and removing any placards on the instrument panel if installed.

### Differences Between This Proposed AD and the EASA AD

The EASA AD requires installing a placard on the instrument panel to warn the flight crew of the erroneous installation until the squibs on each fire extinguisher are exchanged, and then, within 12 months, removing and re-installing the fire extinguishing system to position the squibs in line with the control buttons. This proposed AD would not require installation of the placards or the temporary exchange of

the squibs. Also, this proposed AD would require removing and re-installing the fire extinguisher system within 600 hours TIS or at the next annual inspection, whichever occurs first.

### Costs of Compliance

We estimate that this proposed AD would affect 2 helicopters of U.S. Registry and that labor costs average \$85 per work hour. We expect that removing and installing the fire extinguishing system would require 24 work hours and required parts would cost \$6,367. Based on these estimates, we expect a total cost of \$8,407 per helicopter and \$16,814 for the U.S. fleet.

### 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, 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 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.

We prepared an economic evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

#### List of Subjects in 14 CFR Part 39

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

#### The Proposed Amendment

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

#### PART 39—AIRWORTHINESS DIRECTIVES

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

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

##### § 39.13 [Amended]

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

**Airbus Helicopters:** Docket No. FAA-2015-5807; Directorate Identifier 2015-SW-063-AD.

##### (a) Applicability

This AD applies to Airbus Helicopters Model AS355NP helicopters, certificated in any category, with an Arrius 1A1 fire extinguishing system installed.

##### (b) Unsafe Condition

This AD defines the unsafe condition as an incorrectly connected fire extinguishing discharge system. This condition could result in the fire extinguishing system discharging to the wrong engine compartment, failure of the fire extinguishing system to contain a fire, and loss of control of the helicopter.

##### (c) Comments Due Date

We must receive comments by June 13, 2016.

##### (d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

##### (e) Required Actions

Within 600 hours time-in-service or at the next annual inspection, whichever occurs first, remove and install the fire extinguishing system, and remove any placards on the instrument panel if installed, in accordance with the Accomplishment Instructions, paragraph 3.B. and 3.B.1 through 3.B.2, of Airbus Helicopters Alert Service Bulletin No. AS355-26.00.10, Revision 0, dated July 2, 2015.

##### (f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this

AD. Send your proposal to: George Schwab, Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 10101 Hillwood Pkwy, Fort Worth, TX 76177; telephone (817) 222-5110; email 9-ASW-FTW-AMOC-Requests@faa.gov.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

#### (g) Additional Information

(1) Eurocopter Emergency Alert Service Bulletin No. 26.00.09, Revision 0, dated September 15, 2011, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact Airbus Helicopters, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641-0000 or (800) 232-0323; fax (972) 641-3775; or at <http://www.airbushelicopters.com/techpub>. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N-321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2015-0181, dated August 31, 2015. You may view the EASA AD on the Internet at <http://www.regulations.gov> in the AD Docket.

#### (h) Subject

Joint Aircraft Service Component (JASC) Code: 2620, Extinguishing System.

Issued in Fort Worth, Texas, on April 4, 2016.

#### Scott A. Horn,

*Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.*

[FR Doc. 2016-08247 Filed 4-11-16; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2016-5044; Directorate Identifier 2014-NM-166-AD]

RIN 2120-AA64

#### Airworthiness Directives; Bombardier, Inc. Airplanes

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to adopt a new airworthiness directive (AD) for certain Bombardier, Inc. Model DHC-8-102, -103, and -106 airplanes, and Model DHC-8-200 and -300 series airplanes.

This proposed AD was prompted by a report of heat damage found on a nacelle firewall after an unsuccessful engine ground start and several events of heat damage found on direct current starter/generator terminal block assemblies. This proposed AD would require an inspection for damage on the nacelle firewalls and the terminal block assemblies and to make sure the insulating sleeves are installed and have no damage, and corrective action if necessary. We are proposing this AD to prevent arcing between the firewall and terminal blocks that are missing insulating sleeves on the conductive bushings, which could, in combination with a fuel or hydraulic fluid leak, be an ignition source for a fire.

**DATES:** We must receive comments on this proposed AD by May 27, 2016.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 202-493-2251.

- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Bombardier, Inc., Q-Series Technical Help Desk, 123 Garratt Boulevard, Toronto, Ontario M3K 1Y5, Canada; telephone 416-375-4000; fax 416-375-4539; email [thd.qseries@aero.bombardier.com](mailto:thd.qseries@aero.bombardier.com); Internet <http://www.bombardier.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-2016-5044; 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:**

Assata Dessaline, Aerospace Engineer, Avionics and Flight Test Branch, ANE-172, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516-228-7301; fax 516-794-5531.

**SUPPLEMENTARY INFORMATION:**

**Comments Invited**

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2016-5044; Directorate Identifier 2014-NM-166-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**

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian Airworthiness Directive CF-2014-03R1, dated July 24, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or "the MCAI"), to correct an unsafe condition for certain Bombardier, Inc. Model DHC-8-102, -103, and -106 airplanes, and Model DHC-8-200 and -300 series airplanes. The MCAI states:

There has been one in-service report of heat damage on a nacelle firewall found after an unsuccessful engine ground start. There have also been several reports of heat damage found on Direct Current Starter/Generator terminal block assemblies, part number (P/N) 82450075-001.

The investigation determined that in all cases, the heat damage was caused by arcing between the firewall and terminal blocks with missing insulating sleeves on the conductive bushings. The insulating sleeves may have been inadvertently omitted during the incorporation of Modsum 8/1926, or during the installation of terminal blocks P/N 82450075-001.

Arcing with the firewall becomes an ignition source, creating a potential fire hazard when combined with a fuel or hydraulic fluid leak.

The original issue of this [Canadian] AD mandated the [detailed visual] inspection [for

damage to the nacelle firewalls and to make sure the insulating sleeves are installed and have no damage] and rectification [corrective actions such as installing or replacing insulating sleeves, or replacing a terminal block], as required, of the nacelle firewall and terminal block assembly P/N 82450075-001 installed with Modsum 8/1926.

Revision 1 of this [Canadian] AD is issued to revise the Applicability to ensure that the terminal blocks have the insulating sleeves installed.

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-2016-5044.

**Relevant Service Information Under 1 CFR Part 51**

Bombardier has issued Service Bulletin 8-24-92, Revision A, dated April 11, 2014. This service information describes procedures for an inspection for damage on the nacelle firewalls and the terminal block assemblies and to make sure the insulating sleeves are installed and have no damage, and corrective action if necessary. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

**FAA's Determination and Requirements of This Proposed AD**

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

**Costs of Compliance**

We estimate that this proposed AD affects 75 airplanes of U.S. registry.

We also estimate that it would take about 2 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be \$12,750, or \$170 per product.

In addition, we estimate that any necessary follow-on actions would take about 1 work-hour and require parts costing \$551, for a cost of \$636 per product. We have no way of determining the number of aircraft that might need these actions.

**Authority for This Rulemaking**

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

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

**Regulatory Findings**

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

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

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**List of Subjects in 14 CFR Part 39**

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

**The Proposed Amendment**

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

**PART 39—AIRWORTHINESS DIRECTIVES**

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

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

**§ 39.13 [Amended]**

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

**Bombardier, Inc.:** Docket No. FAA–2016–5044; Directorate Identifier 2014–NM–166–AD.

**(a) Comments Due Date**

We must receive comments by May 27, 2016.

**(b) Affected ADs**

None.

**(c) Applicability**

This AD applies to Bombardier, Inc. airplanes identified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD, certificated in any category, serial numbers 003 through 672 inclusive, on which terminal block part number 82450075–001 is installed.

(1) Model DHC–8–102, –103, and –106 airplanes.

(2) Model DHC–8–201 and –202 airplanes.

(3) Model DHC–8–301, –311, and –315 airplanes.

**(d) Subject**

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

**(e) Reason**

This AD was prompted by a report of one event of heat damage found on a nacelle firewall after an unsuccessful engine ground start and several events of heat damage found on direct current starter/generator terminal block assemblies. We are issuing this AD to prevent arcing between the firewall and terminal blocks that are missing insulating sleeves on the conductive bushings, which could, in combination with a fuel or hydraulic fluid leak, be an ignition source for a fire.

**(f) Compliance**

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

**(g) Inspection and Corrective Action**

Within 2,500 flight cycles or 14 months after the effective date of this AD, whichever occurs first, perform a detailed visual inspection of the right-hand side and left-hand side nacelle firewalls and terminal block assemblies, as defined in Bombardier Service Bulletin 8–24–92, Revision A, dated April 11, 2014, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 8–24–92, Revision A, dated April 11, 2014.

(1) If the inspection finds no damage on the engine firewalls and the terminal blocks, and that the insulating sleeves are installed on both terminal blocks, no further action is required by this AD.

(2) If the inspection finds that no insulating sleeves are installed, or the existing sleeves are damaged, and there is no damage to the nacelle firewall and terminal block, before further flight, install the replacement insulating sleeves, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 8–24–92, Revision A, dated April 11, 2014.

(3) If the inspection finds that no insulating sleeves are installed, or any existing sleeve is damaged, and there is no damage to the nacelle firewall, but there is damage to the terminal block, before further flight, replace the terminal block assembly (which includes insulating sleeves), in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 8–24–92, Revision A, dated April 11, 2014.

(4) If the inspection finds that no insulating sleeves are installed and there is damage to the nacelle firewall and the terminal block, repair the damage using a method approved by the Manager, New York Aircraft Certification Office (ACO), ANE–170, Engine and Propeller Directorate, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO).

**(h) Credit for Previous Actions**

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Bombardier Service Bulletin 8–24–92, dated September 25, 2013, which is not incorporated by reference in this AD.

**(i) Other FAA AD Provisions**

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO, ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *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, New York ACO, ANE–170, Engine and Propeller Directorate, FAA; or TCCA; or Bombardier, Inc.'s TCCA DAO. If approved by the DAO, the approval must include the DAO-authorized signature.

**(j) Related Information**

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian Airworthiness Directive CF–2014–03R1, dated July 24, 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 Docket No. FAA–2016–5044.

(2) For service information identified in this AD, contact Bombardier, Inc., Q-Series Technical Help Desk, 123 Garratt Boulevard, Toronto, Ontario M3K 1Y5, Canada; telephone 416–375–4000; fax 416–375–4539;

email [thd.qseries@aero.bombardier.com](mailto:thd.qseries@aero.bombardier.com); Internet <http://www.bombardier.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 March 26, 2016.

**Jeffrey E. Duven,**

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–08266 Filed 4–11–16; 8:45 am]

**BILLING CODE 4910–13–P**

**DEPARTMENT OF TRANSPORTATION****Federal Aviation Administration****14 CFR Part 39**

**[Docket No. FAA–2016–5468; Directorate Identifier 2015–NM–021–AD]**

**RIN 2120–AA64**

**Airworthiness Directives; The Boeing Company Airplanes**

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to adopt a new airworthiness directive (AD) for all The Boeing Company Model 737–600, –700, –700C, –800, and –900 series airplanes. This proposed AD was prompted by reports of paint deterioration on the surface of the main landing gear (MLG) and the early onset of corrosion in the trunnion bore of the MLG outer cylinder. This proposed AD would require identifying affected parts, repetitive external surface detailed inspection for damage of affected parts, and related investigative and corrective actions if necessary. For certain airplanes, this AD also would require a detailed inspection and bushing replacement of the trunnion bore, and related investigative and corrective action if necessary. We are proposing this AD to prevent stress corrosion cracking of the external surfaces of the MLG, which could result in a fracture of the MLG and consequent MLG collapse.

**DATES:** We must receive comments on this proposed AD by May 27, 2016.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–



30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

- **Hand Delivery:** Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.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. It is also available on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2016-5468.

#### *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-2016-5468; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

#### **FOR FURTHER INFORMATION CONTACT:**

Alan Pohl, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6450; fax: 425-917-6590; email: [alan.pohl@faa.gov](mailto:alan.pohl@faa.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **Comments Invited**

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2016-5468; Directorate Identifier 2015-NM-021-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this

proposed AD because of those comments.

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

#### **Discussion**

We received reports from several operators of paint deterioration on the surface of the MLG and early onset of corrosion in the trunnion bore of the MLG outer cylinder. A maintenance repair and overhaul (MRO) facility observed forward trunnion bore corrosion on a right MLG while installing new bushings. Another MRO disclosed that between 2007 and 2010, the primer used on the landing gear components did not comply with Boeing Material Specification (BMS) 10-79. Also, paint chip and trunnion bore analysis showed that unqualified primer was used; primer application was up to 5 times too thick while enamel was too thin; there was early deterioration of the fillet seal at the trunnion bore; and the trunnion bushing installation process, which may have damaged the finish on the bore, did not follow the standard overhaul practices manual. This condition, if not corrected, could result in a fracture of the MLG and consequent MLG collapse.

#### **Related Service Information Under 1 CFR Part 51**

We reviewed Boeing Special Attention Service Bulletin 737-32-1486, dated November 6, 2014, as revised by Boeing Special Attention Service Bulletin 737-32-1486, Revision 1, dated April 1, 2015. The service information describes procedures for identifying affected parts, repetitive external surface detailed inspection for damage of affected parts, and related investigative and corrective actions if necessary. For certain airplanes, this AD also would require a detailed inspection and bushing replacement of the trunnion bore, and related investigative and corrective action if necessary. The service information also describes procedures for certain airplanes that include a detailed inspection of the trunnion bore, and corrective actions. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

#### **FAA's Determination**

We are proposing this AD because we evaluated all the relevant information

and determined the unsafe condition described previously is likely to exist or develop in other products of these same type designs.

#### **Proposed AD Requirements**

This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under "Differences Between this Proposed AD and the Service Information."

The phrase "corrective actions" is used in this proposed AD. "Corrective actions" correct or address any condition found. Corrective actions in an AD could include, for example, repairs.

The phrase "related investigative actions" is used in this proposed AD. "Related investigative actions" are follow-on actions that (1) are related to the primary action, and (2) further investigate the nature of any condition found. Related investigative actions in an AD could include, for example, inspections.

#### **Differences Between This Proposed AD and the Service Information**

Boeing Special Attention Service Bulletin 737-32-1486, dated November 6, 2014, as revised by Boeing Special Attention Service Bulletin 737-32-1486, Revision 1, dated April 1, 2015, specifies to contact the manufacturer for instructions on how to repair certain conditions, but this proposed AD would require repairing those conditions in one of the following ways:

- In accordance with a method that we approve; or
- Using data that meet the certification basis of the airplane, and that have been approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) whom we have authorized to make those findings.

While the effectivity of Boeing Special Attention Service Bulletin 737-32-1486, dated November 6, 2014, as revised by Boeing Special Attention Service Bulletin 737-32-1486, Revision 1, dated April 1, 2015, is limited to those airplanes that are listed, the applicability of this AD affects all The Boeing Company Model 737-600, -700, -700C, -800, and -900 series airplanes.

#### **Clarification of Affected MLGs**

An MLG overhauled by SAFRAN Messier-Bugatti-Dowty outside of the Boeing Exchange program from June 1, 2009, to July 31, 2013, would also be affected by this proposed AD.

**Costs of Compliance**

We estimate that this proposed AD affects 33 airplanes of U.S. registry.

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

**ESTIMATED COSTS**

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
External surface detailed inspection.	Up to 16 work-hours × \$85 per hour = \$1,360 per inspection cycle.	\$0 .....	\$1,360 per inspection cycle.	Up to \$44,880 per inspection cycle.
Outer Cylinder assembly trunnion bore detailed inspection and bushing replacement (G1-2, configuration 1).	70 work-hours × \$85 per hour = \$5,950.	Negligible .....	\$5,950 .....	\$196,350.

We estimate the following costs to do any necessary replacements that would

be required based on the results of the proposed inspection. We have no way of

determining the number of aircraft that might need this replacement.

**ON-CONDITION COSTS**

Action	Labor cost	Cost per product
Outer cylinder assembly replacement (if required as a result of the outer cylinder trunnion bore detailed inspection).	28 work-hours × \$85 per hour = \$2,380 .....	\$2,380

We have received no definitive data that would enable us to provide cost estimates for certain on-condition actions (MLG external surface repair, MLG component replacement, outer cylinder repair, and MLG replacement) specified in this proposed AD.

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

The previous info is based on known airplanes. However, the MLG may have been overhauled outside of the Boeing Exchange Program as specified in the Clarification of Affected MLGs section of this proposed AD.

**Authority for This Rulemaking**

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

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: “General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures

the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

**Regulatory Findings**

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

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

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),
- (3) Will not affect intrastate aviation in Alaska, and
- (4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**List of Subjects in 14 CFR Part 39**

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

**The Proposed Amendment**

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

**PART 39—AIRWORTHINESS DIRECTIVES**

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

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

**§ 39.13 [Amended]**

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

**The Boeing Company:** Docket No. FAA–2016–5468; Directorate Identifier 2015–NM–021–AD.

**(a) Comments Due Date**

We must receive comments by May 27, 2016.

**(b) Affected ADs**

None.

**(c) Applicability**

This AD applies to all The Boeing Company Model 737–600, –700, –700C, –800, and –900 series airplanes, certificated in any category.

**(d) Subject**

Air Transport Association (ATA) of America Code 32, Landing Gear.

**(e) Unsafe Condition**

This AD was prompted by reports of paint deterioration on the surface of the main

landing gear (MLG) and early onset of corrosion in the trunnion bore of the MLG outer cylinder. We are issuing this AD to prevent stress corrosion cracking of the external surfaces of the MLG, which could result in a fracture of the MLG and consequent MLG collapse.

**(f) Compliance**

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

**(g) Inspection for Affected Part/Serial Numbers**

At the applicable time specified in table 1 of paragraph 1.E., “Compliance,” of Boeing Special Attention Service Bulletin 737–32–1486, dated November 6, 2014, as revised by Boeing Special Attention Service Bulletin 737–32–1486, Revision 1, dated April 1, 2015, except as required by paragraph (k)(1) of this AD: Do the actions specified in paragraphs (g)(1) and (g)(2) of this AD in order to identify affected parts.

(1) Inspect the MLG to determine if it has any component installation or side strut assembly having a part number and serial number listed in Appendix D of Boeing Special Attention Service Bulletin 737–32–1486, dated November 6, 2014, as revised by Boeing Special Attention Service Bulletin 737–32–1486, Revision 1, dated April 1, 2015; except that the “Variable Number” column of Appendix D is to be disregarded in determining affected part and serial numbers. A MLG that has any MLG component installation or side strut assembly having a part number and serial number listed in Appendix D of Boeing Special Attention Service Bulletin 737–32–1486, dated November 6, 2014, as revised by Boeing Special Attention Service Bulletin 737–32–1486, Revision 1, dated April 1, 2015, is an affected part. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number and serial number of the MLG component installation and side strut assembly can be conclusively identified from that review.

(2) Do a records review to determine if the MLG has been overhauled by SAFRAN Messier-Bugatti-Dowty outside of the Boeing Exchange program from June 1, 2009 to July 31, 2013. If the MLG has been overhauled by SAFRAN Messier-Bugatti-Dowty outside of the Boeing Exchange program from June 1, 2009 to July 31, 2013, that MLG is an affected part. If the records review cannot conclusively determine that an overhauled MLG was overhauled by an MRO other than SAFRAN Messier-Bugatti-Dowty, or if the records review cannot conclusively determine that an MLG overhauled by SAFRAN Messier-Bugatti-Dowty was part of the Boeing Exchange program from June 1, 2009 to July 31, 2013; that MLG is an affected part.

**(h) Requirements for Affected Parts**

If any affected part is identified during the inspection or records review required by paragraph (g) of this AD: At the applicable time specified in table 3 of paragraph 1.E., “Compliance,” of Boeing Special Attention Service Bulletin 737–32–1486, dated November 6, 2014, as revised by Boeing

Special Attention Service Bulletin 737–32–1486, Revision 1, dated April 1, 2015, except as required by paragraph (k)(1) of this AD: Do detailed inspections of the external surfaces of the MLG, and do all applicable related investigative and corrective actions, in accordance with Parts 1, 3, and 4 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–32–1486, dated November 6, 2014, as revised by Boeing Special Attention Service Bulletin 737–32–1486, Revision 1, dated April 1, 2015, except as required by paragraph (k)(2) of this AD. Repeat the inspections thereafter at the applicable time specified in table 3 of paragraph 1.E., “Compliance,” of Boeing Special Attention Service Bulletin 737–32–1486, dated November 6, 2014, as revised by Boeing Special Attention Service Bulletin 737–32–1486, Revision 1, dated April 1, 2015. All applicable related investigative and corrective actions must be done before further flight.

**(i) Additional Actions for Groups 1 and 2, Configuration 1**

For airplanes that are identified as Groups 1 and 2, Configuration 1, in Boeing Special Attention Service Bulletin 737–32–1486, dated November 6, 2014, as revised by Boeing Special Attention Service Bulletin 737–32–1486, Revision 1, dated April 1, 2015, and that have an affected part identified during the inspection or records review required by paragraph (g) of this AD: At the applicable time specified in table 4 of Paragraph 1.E., “Compliance,” of Boeing Special Attention Service Bulletin 737–32–1486, dated November 6, 2014, as revised by Boeing Special Attention Service Bulletin 737–32–1486, Revision 1, dated April 1, 2015, except as required by paragraph (k)(1) of this AD, do a detailed inspection and bushing replacement of the MLG trunnion bore, and do all applicable related investigative and corrective actions, in accordance with Parts 2, 5, and 6 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–32–1486, dated November 6, 2014, as revised by Boeing Special Attention Service Bulletin 737–32–1486, Revision 1, dated April 1, 2015, except as required by paragraph (k)(2) of this AD.

**(j) Terminating Action**

(1) MLG replacement in accordance with Part 8 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–32–1486, dated November 6, 2014, as revised by Boeing Special Attention Service Bulletin 737–32–1486, Revision 1, dated April 1, 2015, terminates the requirements of paragraphs (g), (h), and (i) of this AD for that MLG only.

(2) MLG component replacement in accordance with Part 4 of the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–32–1486, dated November 6, 2014, as revised by Boeing Special Attention Service Bulletin 737–32–1486, Revision 1, dated April 1, 2015, terminates the requirements of paragraph (h) of this AD for that component only.

(3) MLG outer cylinder replacement in accordance with Part 7 of the

Accomplishment Instructions of Boeing Special Attention Service Bulletin 737–32–1486, dated November 6, 2014, as revised by Boeing Special Attention Service Bulletin 737–32–1486, Revision 1, dated April 1, 2015, terminates the requirements of paragraph (i) of this AD for that component only.

**(k) Exceptions to Service Information Specifications**

(1) Where paragraph 1.E., “Compliance,” of Boeing Special Attention Service Bulletin 737–32–1486, dated November 6, 2014, as revised by Boeing Special Attention Service Bulletin 737–32–1486, Revision 1, dated April 1, 2015, specifies a compliance time “after the original issue date of this service bulletin,” this AD requires compliance within the specified compliance time after the effective date of this AD.

(2) Although Boeing Special Attention Service Bulletin 737–32–1486, dated November 6, 2014, as revised by Boeing Special Attention Service Bulletin 737–32–1486, Revision 1, dated April 1, 2015, specifies to contact Boeing for repair instructions, and specifies that action as “RC” (Required for Compliance), this AD requires repair before further flight using a method approved in accordance with the procedures specified in paragraph (m) of this AD.

**(l) Parts Installation Prohibition**

As of the effective date of this AD, no person may install the following on any airplane identified in paragraph (c) of this AD, unless the MLG has been overhauled using a method approved in accordance with the procedures specified in paragraph (m) of this AD:

(1) An MLG having a part number and serial number identified in Appendix D to Boeing Special Attention Service Bulletin 737–32–1486, dated November 6, 2014, as revised by Boeing Special Attention Service Bulletin 737–32–1486, Revision 1, dated April 1, 2015.

(2) An MLG that was overhauled from June 1, 2009, to July 31, 2013, by SAFRAN Messier-Bugatti-Dowty.

**(m) Alternative Methods of Compliance (AMOCs)**

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

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing

Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) Except as required by paragraph (k)(2) of this AD: For service information that contains steps that are labeled as RC, the provisions of paragraphs (m)(4)(i) and (m)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

#### (n) Related Information

(1) For more information about this AD, contact Alan Pohl, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Seattle ACO, 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6450; fax: 425-917-6590; email: [alan.pohl@faa.gov](mailto:alan.pohl@faa.gov).

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.com>. For information on the availability of this material at the FAA, 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.

Issued in Renton, Washington, on March 31, 2016.

#### Victor Wicklund,

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2016-08349 Filed 4-11-16; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA-2016-5579; Directorate Identifier 2016-CE-010-AD]

RIN 2120-AA64

#### Airworthiness Directives; Textron Aviation Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to supersede Airworthiness Directive (AD) 2008-15-06, which applies to certain Textron Aviation Inc. Models 175 and 175A airplanes (type certificate previously held by Cessna Aircraft Company). AD 2008-15-06 currently requires checking the airplane logbook to determine if the original engine mounting brackets have been replaced. If the original engine mounting brackets are still installed, the AD requires repetitively inspecting those brackets for cracks and replacing any cracked engine mounting bracket until all four original engine mounting brackets are replaced. Replacing all four original engine mounting brackets terminates the actions required in AD 2008-15-06. Since we issued AD 2008-15-06, we have determined that the applicability needs to be changed to add a serial number and take one out. This proposed AD would retain the actions required in AD 2008-15-06 and would change the Applicability section. We are proposing this AD to correct the unsafe condition on these products.

**DATES:** We must receive comments on this proposed AD by May 27, 2016.

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

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

For service information identified in this NPRM, contact Cessna Aircraft Company, Product Support, P.O. Box 7706, Wichita, Kansas 67277; telephone: (316) 517-5800; fax: (316) 942-9006; Internet: [www.cessna.txtav.com](http://www.cessna.txtav.com). You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148.

#### 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-2016-5579; or in person at the Docket

Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

**FOR FURTHER INFORMATION CONTACT:** Gary Park, Aerospace Engineer, Wichita Aircraft Certification Office, 1801 Airport Road, Room 100, Wichita, Kansas 67209; telephone: (316) 946-4123; fax: (316) 946-4107; email: [gary.park@faa.gov](mailto:gary.park@faa.gov).

#### SUPPLEMENTARY INFORMATION:

##### Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2016-5579; Directorate Identifier 2016-CE-010-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

#### Discussion

On July 15, 2008, we issued AD 2008-15-06, Amendment 39-15618 (73 FR 43845, July 29, 2008), ("AD 2008-15-06"), for certain Textron Aviation Inc. Models 175 and 175A airplanes (type certificate previously held by Cessna Aircraft Company). AD 2008-15-06 requires you to check the airplane logbook to determine if the original engine mounting brackets have been replaced. If the original engine mounting brackets are still installed, this AD requires you to repetitively inspect those brackets for cracks and replace any cracked engine mounting bracket. After replacing all four original engine mounting brackets, no further action will be required by this AD. AD 2008-15-06 resulted from a report of the engine detaching from the firewall on a Cessna Model 175 airplane during landing. We issued AD 2008-15-06 to detect and correct cracks in the engine

mounting brackets, which could result in failure of the engine mounting bracket. This failure could lead to the engine detaching from the firewall.

**Actions Since AD 2008–15–06 Was Issued**

Since we issued AD 2008–15–06, we have determined that the applicability for Model 175A airplanes needs to be changed. We have determined that a serial number has been inadvertently included in the applicability and a serial number has been inadvertently omitted from the applicability.

**Related Service Information Under 1 CFR Part 51**

We reviewed Cessna Single Engine Service Bulletin SEB07–2, Revision 2, dated June 18, 2007. The service information describes procedures for inspecting the upper and lower engine mounting brackets on both the left and right sides for cracks and replacing cracked engine mounting brackets. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

**FAA’s Determination**

We are proposing this AD because we evaluated all the relevant information

and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

**Proposed AD Requirements**

This proposed AD would retain the requirements of AD 2008–15–06 and would add a serial number to the applicability and take one out.

**Costs of Compliance**

We estimate that this AD would affect 1,218 airplanes in the U.S. registry.

We estimate the following costs to do each proposed inspection:

Labor cost	Parts cost	Total cost per airplane	Total cost on U.S. operators
7.5 work-hours × \$80 per hour = \$600 .....	Not applicable .....	\$600	\$730,800

We estimate the following costs to do any necessary proposed replacements:

Labor cost	Parts cost	Total cost per airplane
3 work-hours per bracket × \$80 per hour = \$240 per bracket. 4 brackets per airplane × \$240 per bracket = \$960.	\$200 per bracket. 4 × \$200 = \$800 for all 4 brackets.	\$440 per bracket. \$1,760 to replace all 4 brackets.

There is no estimated cost of compliance difference between this proposed AD and AD 2008–15–06 since there is no change in the number of affected airplanes or in the proposed actions. The cost impact on the public would be in the removal of serial number 691 and the addition of serial number 619.

**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 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 that the proposed regulation:

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),
- (3) Will not affect intrastate aviation in Alaska, and
- (4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

**List of Subjects in 14 CFR Part 39**

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

**The Proposed Amendment**

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

**PART 39—AIRWORTHINESS DIRECTIVES**

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

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

**§ 39.13 [Amended]**

- 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2008–15–06, Amendment 39–15618 (73 FR 43845, July 29, 2008), and adding the following new AD:

**Textron Aviation Inc.:** Docket No. FAA–2016–5579; Directorate Identifier 2016–CE–010.

**(a) Comments Due Date**

The FAA must receive comments on this AD action by May 27, 2016.

**(b) Affected ADs**

This AD replaces AD 2008–15–06, Amendment 39–15618 (73 FR 43845, July 29, 2008) (“AD 2008–15–06”).

**(c) Applicability**

This AD applies to the following Textron Aviation Inc. airplane models and serial

numbers (type certificate previously held by Cessna Aircraft Company) that are certificated in any category.

(1) Airplanes previously affected by AD 2008–15–06

Model	Serial Nos.	Year manufactured
(1) 175 .....	55001 through 55703.	1958.
(2) 175 .....	55704 through 56238.	1959.
(3) 175 .....	28700A, 626, and 640.	1958 and 1959.
(4) 175A .....	56239 through 56777.	1960.

(2) New airplane affected by this AD:

Model	Serial Nos.	Year manufactured
175A .....	619	1960.

#### (d) Subject

Joint Aircraft System Component (JASC)/ Air Transport Association (ATA) of America Code 71, Power Plant.

#### (e) Unsafe Condition

This AD was prompted by the determination that an airplane needs to be added to the Applicability section and an airplane needs to be removed from the Applicability section. We are issuing this AD to detect and correct cracks in the engine mounting brackets, which could result in failure of the engine mounting bracket. This failure could lead to the engine detaching from the firewall.

#### (f) Compliance

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

#### (g) Airplane Logbook Check

(1) Check the airplane logbook to determine if all four of the original engine mounting brackets have been replaced. Do the logbook check at the following compliance time, as applicable. The owner/operator holding at least a private pilot certificate as authorized by section 43.7 may do this action.

(i) *For airplanes previously affected by AD 2008–15–06:* Within the next 30 days after September 2, 2008 (the effective date retained from AD 2008–15–06).

(ii) *For the new airplane affected by this AD:* Within the next 30 days after the effective date of this AD.

(2) If you can positively determine that all four of the original engine mounting brackets have been replaced, no further action is required. Make an entry into the aircraft logbook showing compliance with this portion of the AD in accordance with 14 CFR 43.9. The owner/operator holding at least a private pilot certificate as authorized by section 43.7 may do this action.

(3) If you cannot positively determine that all four of the original engine mounting brackets have been replaced, inspect each of the upper and lower engine mounting brackets on both the left and right sides for cracks following Cessna Single Engine Service Bulletin SEB07–2, Revision 2, dated June 18, 2007. Do the inspections at the following compliance times, as applicable.

(i) *For airplanes previously affected by AD 2008–15–06:* Initially inspect within the next 12 months after September 2, 2008 (the effective date retained from AD 2008–15–06). If no cracks are found, repetitively inspect thereafter at intervals not to exceed 500 hours time-in-service (TIS) until all four of the original engine mounting brackets are replaced.

(ii) *For the new airplane affected by this AD:* Initially inspect within the next 12 months after the effective date of this AD. If no cracks are found, repetitively inspect thereafter at intervals not to exceed 500 hours TIS until all four of the original engine mounting brackets are replaced.

#### (h) Engine Mounting Bracket Replacement

*For all airplanes affected by this AD:* If cracks are found in any of the engine mounting brackets during any inspection required in paragraph (g)(3) of this AD, including all subparagraphs, before further flight after the inspection in which cracks are found, replace the cracked engine mounting bracket(s) following Cessna Single Engine Service Bulletin SEB07–2, Revision 2, dated June 18, 2007. Replacing the cracked engine mounting bracket terminates the repetitive inspections required in paragraphs (g)(3)(i) and (g)(3)(ii) of this AD only for the replaced engine mounting bracket.

#### (i) Terminating Action

To terminate the repetitive inspections required in paragraphs (g)(3)(i) and (g)(3)(ii) of this AD, you may replace all four original engine mounting brackets following Cessna Single Engine Service Bulletin SEB07–2, Revision 2, dated June 18, 2007, at the following compliance times, as applicable.

(1) *For airplanes previously affected by AD 2008–15–06:* At any time before or after the initial inspection required in paragraph (g)(3)(i) of this AD.

(2) *For the new airplane affected by this AD:* At any time before or after the initial inspection required in paragraph (g)(3)(ii) of this AD.

#### (j) Engine Mounting Bracket Disposal

*For all airplanes affected by this AD:* Before further flight after the engine mounting bracket is removed for replacement, dispose of every replaced bracket following 14 CFR 43.10, paragraph (c)(6), which states the following: “Mutilation. The part may be mutilated to deter its installation in a type certificated product. The mutilation must render the part beyond repair and incapable of being reworked to appear to be airworthy.”

#### (k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Wichita Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if

requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (l) of this AD.

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

(3) AMOCs approved for AD 2008–15–06 are approved as AMOCs for the corresponding provisions of this AD.

#### (l) Related Information

(1) For more information about this AD, contact Gary Park, Aerospace Engineer, Wichita ACO, 1801 Airport Road, Room 100, Wichita, Kansas 67209; telephone: (316) 946–4123; fax: (316) 946–4107, email: [gary.park@faa.gov](mailto:gary.park@faa.gov).

(2) For service information identified in this AD, contact Cessna Aircraft Company, Product Support, P.O. Box 7706, Wichita, Kansas 67277; telephone: (316) 517–5800; fax: (316) 942–9006; Internet: [www.cessna.txtav.com](http://www.cessna.txtav.com). You may view this referenced service information at the FAA, FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on April 4, 2016.

#### Pat Mullen,

*Acting Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2016–08259 Filed 4–11–16; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. FAA–2016–5463; Directorate Identifier 2016–NM–013–AD]

RIN 2120–AA64

#### Airworthiness Directives; Bombardier, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

**SUMMARY:** We propose to adopt a new airworthiness directive (AD) for certain Bombardier, Inc. Model CL–600–2C10 (Regional Jet Series 700, 701, & 702), Model CL–600–2D15 (Regional Jet Series 705), Model CL–600–2D24 (Regional Jet Series 900), and Model CL–600–2E25 (Regional Jet Series 1000) airplanes. This proposed AD was prompted by reports of corrosion found on the slat and flap torque tubes in the

slat and flap control system. This proposed AD would require replacement of the slat and flap torque tubes in the slat and flap control system. We are proposing this AD to prevent rupture of a corroded slat or flap torque tube. This condition could result in an inoperative slat or flap system and consequent reduced controllability of the airplane.

**DATES:** We must receive comments on this proposed AD by May 27, 2016.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 202-493-2251.

- *Mail:* U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone: 514-855-5000; fax: 514-855-7401; email: [thd.crj@aero.bombardier.com](mailto:thd.crj@aero.bombardier.com); Internet: <http://www.bombardier.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-2016-5463; 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:** Cesar Gomez, Aerospace Engineer, Airframe and Mechanical Systems Branch, ANE-171, FAA, New York Aircraft Certification Office (ACO), 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: 516-228-7318; fax: 516-794-5531.

**SUPPLEMENTARY INFORMATION:**

**Comments Invited**

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include “Docket No. FAA-2016-5463; Directorate Identifier 2016-NM-013-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**

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian AD CF-2016-03R1, dated February 18, 2016 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Bombardier, Inc. Model CL-600-2C10 (Regional Jet Series 700, 701, & 702), Model CL-600-2D15 (Regional Jet Series 705), Model CL-600-2D24 (Regional Jet Series 900), and Model CL-600-2E25 (Regional Jet Series 1000) airplanes. The MCAI states:

There have been a number of reports of corrosion found on the torque tubes in the slat and flap control system. Investigation revealed that the current design of the flap and slat torque tubes do not have proper corrosion protection and are not entirely

sealed which leads to moisture ingress and internal corrosion. A corroded tube may rupture resulting in an inoperative slat or flap system, or in a worst case scenario, could result in reduced controllability of the aeroplane. This [Canadian] AD mandates the replacement of affected slat and flap system torque tubes with [new or] modified torque tubes.

This [Canadian] AD was revised to add the statement that accomplishment of the initial Service Bulletin (SB) 670BA-27-067, dated 15 January 2015 also meets the requirements of this AD and to correct the editorial error for the release date of SB 670BA-27-067, Revision A.

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-2016-5463.

**Related Service Information Under 1 CFR Part 51**

We reviewed Bombardier Service Bulletin 670BA-27-067, Revision A, dated February 23, 2015. This service information describes procedures for replacement of the slat and flap torque tubes in the slat and flap control system. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

**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 509 airplanes of U.S. registry.

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

**ESTIMATED COSTS**

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replacement of the slat and flap torque tubes	34 work-hours × \$85 per hour = \$2,890 .....	\$105,000	\$107,890	\$54,916,010

According to the parts manufacturer, some of the costs of this proposed AD

may be covered under warranty, thereby reducing the cost impact on affected

individuals. We do not control warranty coverage for affected individuals. As a

result, we have included all costs in our cost estimate.

### Authority for This Rulemaking

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

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

### Regulatory Findings

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

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

1. Is not a "significant regulatory action" under Executive Order 12866;
2. Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

### List of Subjects in 14 CFR Part 39

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

### The Proposed Amendment

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

## PART 39—AIRWORTHINESS DIRECTIVES

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

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

### § 39.13 [Amended]

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

**Bombardier, Inc.:** Docket No. FAA-2016-5463; Directorate Identifier 2016-NM-013-AD.

#### (a) Comments Due Date

We must receive comments by May 27, 2016.

#### (b) Affected ADs

None.

#### (c) Applicability

This AD applies to the airplanes, certificated in any category, identified in paragraphs (c)(1), (c)(2), (c)(3), and (c)(4) of this AD.

(1) Bombardier, Inc. Model CL-600-2C10 (Regional Jet Series 700, 701, & 702) airplanes, serial numbers 10002 through 10342 inclusive.

(2) Bombardier, Inc. Model CL-600-2D15 (Regional Jet Series 705) airplanes, serial numbers 15001 through 15361 inclusive.

(3) Bombardier, Inc. Model CL-600-2D24 (Regional Jet Series 900) airplanes, serial numbers 15001 through 15361 inclusive.

(4) Bombardier, Inc. Model CL-600-2E25 (Regional Jet Series 1000) airplanes, serial numbers 19001 through 19041 inclusive.

#### (d) Subject

Air Transport Association (ATA) of America Code 27, Flight controls.

#### (e) Reason

This AD was prompted by reports of corrosion found on the slat and flap torque tubes in the slat and flap control system. We are issuing this AD to prevent rupture of a corroded slat or flap torque tube. This condition could result in an inoperative slat or flap system and consequent reduced controllability of the airplane.

#### (f) Compliance

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

#### (g) Replace Slat and Flap Torque Tubes in the Slat and Flap Control System

Within the compliance times specified in paragraph (g)(1), (g)(2), or (g)(3) of this AD, as applicable: Replace the slat and flap torque tubes in the slat and flap control system with new or modified slat and flap torque tubes, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 670BA-27-067, Revision A, dated February 23, 2015.

(1) For airplanes that have accumulated 28,000 total flight hours or less as of the effective date of this AD, or with 137 months or less since the date of issuance of the original Canadian certificate of airworthiness or date of issuance of the original Canadian export certificate of airworthiness as of the effective date of this AD: Before the accumulation of 34,000 total flight hours or within 167 months since the date of issuance

of the original Canadian certificate of airworthiness or date of issuance of the original Canadian export certificate of airworthiness, whichever occurs first.

(2) For airplanes that have accumulated more than 28,000 total flight hours but not more than 36,000 total flight hours as of the effective date of this AD, and with more than 137 months but not more than 176 months since the date of issuance of the original Canadian certificate of airworthiness or date of issuance of the original Canadian export certificate of airworthiness as of the effective date of this AD: At the earlier of the times specified in paragraphs (g)(2)(i) and (g)(2)(ii) of this AD.

(i) Within 6,000 flight hours or 30 months, whichever occurs first, after the effective date of this AD.

(ii) Before the accumulation of 38,000 total flight hours, or within 186 months since the date of issuance of the original Canadian certificate of airworthiness or date of issuance of the original Canadian export certificate of airworthiness, whichever occurs first.

(3) For airplanes that have accumulated more than 36,000 total flight hours as of the effective date of this AD, or with more than 176 months since the date of issuance of the original Canadian certificate of airworthiness or date of issuance of the original Canadian export certificate of airworthiness as of the effective date of this AD: Within 2,000 flight hours or 10 months, whichever occurs first, after the effective date of this AD.

#### (h) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Bombardier Service Bulletin 670BA-27-067, dated January 15, 2015, which is not incorporated by reference in this AD.

#### (i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York Aircraft Certification Office (ACO), ANE-170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516-228-7300; fax: 516-794-5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *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, New York ACO, ANE-170, FAA; or Transport Canada Civil Aviation



(TCCA); or Bombardier, Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

#### (j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF-2016-03R1, dated February 18, 2016, 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 Docket No. FAA-2016-5463.

(2) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone: 514-855-5000; fax: 514-855-7401; email: [thd.crj@aero.bombardier.com](mailto:thd.crj@aero.bombardier.com); Internet: <http://www.bombardier.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 March 31, 2016.

**Victor Wicklund,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2016-08250 Filed 4-11-16; 8:45 am]

**BILLING CODE 4910-13-P**

## POSTAL REGULATORY COMMISSION

### 39 CFR Part 3020

[Docket No. RM2016-8; Order No. 3213]

#### Mail Classification Schedule

**AGENCY:** Postal Regulatory Commission.

**ACTION:** Proposed rulemaking.

**SUMMARY:** The Commission is proposing rules which amend existing rules related to the Mail Classification Schedule and its associated product lists. The proposed rules revise some existing rules in order to better conform with current Commission practices related to the Mail Classification Schedule. The Commission invites public comment on the proposed rules.

**DATES:** *Comments are due:* May 12, 2016.

**FOR FURTHER INFORMATION CONTACT:** David A. Trissell, General Counsel, at 202-789-6820.

#### SUPPLEMENTARY INFORMATION:

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#### I. Introduction

This rulemaking is initiated by the Postal Regulatory Commission

(Commission) to fulfill its responsibilities under the Postal Accountability and Enhancement Act (PAEA), Public Law 109-435, 120 Stat. 3198 (2006). The proposed rules amend existing rules concerning the Mail Classification Schedule (MCS) and the associated market dominant and competitive product lists. The proposals amend existing rules to conform to the current practice of publishing the MCS on the Commission's Web site at [www.prc.gov](http://www.prc.gov), noticing changes to the market dominant and competitive product lists in the **Federal Register**, and publishing the market dominant and competitive product lists in the *Code of Federal Regulations* (CFR).

The proposed rules replace existing 39 CFR part 3020, subpart A in its entirety. Conforming changes also are proposed for 39 CFR part 3020, subparts B, C, and D. The proposed text for these rules appears after the signature of this Order.

#### II. History

On October 29, 2007, the Commission issued Order No. 43, which in part established rules concerning the MCS, and the market dominant and competitive product lists.<sup>1</sup> It also directed publication of an MCS outline in the CFR that was limited to a table of contents and the market dominant and competitive product lists. Order No. 43, Appendix A. These rules, including the appendix, were codified at 39 CFR part 3020.

The Commission, in Docket No. RM2007-1, also began the process of developing a comprehensive MCS.<sup>2</sup> This task was not complete at the time the Commission issued Order No. 43.

When an initial proposed MCS was complete, the Commission initiated Docket No. RM2011-8 to incorporate it into the CFR.<sup>3</sup> The proposed MCS was to replace the existing outline of the MCS. The Commission solicited and received comments on both the proposed MCS and the corresponding rules. The suggestions provided in the

<sup>1</sup> Docket No. RM2007-1, Order Establishing Ratemaking Regulations for Market Dominant and Competitive Products, October 29, 2007, at 99-108, 138-154 (Order No. 43); 72 FR 64155, November 15, 2007.

<sup>2</sup> Docket No. RM2007-1, Order No. 26, Order Proposing Regulations to Establish a System of Ratemaking, August 15, 2007, at 2, 82-83; 72 FR 50744, September 4, 2007. *See also* Order No. 43 at 99.

<sup>3</sup> Docket No. RM2011-8, Order No. 666, Notice of Proposed Rulemaking Concerning Mail Classification Schedule, February 7, 2011; Docket No. RM2011-8, Order No. 758, Notice of Proposed Rulemaking Concerning Mail Classification Schedule (Revising Order No. 666), July 12, 2011; 76 FR 51311 (Aug. 18, 2011) (to be codified at 39 CFR part 3020, subpart A).

comments were extremely helpful in further developing the MCS and have been incorporated into the rule proposals appearing in the instant rulemaking.

From an administrative perspective, the rulemaking also required the Commission to develop internal procedures for implementing the proposed rules. This included procedures for publishing timely updates to the MCS and the associated product lists appearing in the CFR. Because of the continuous flow of Postal Service proposals to add or modify products, the Commission recognized that keeping the CFR-published MCS and the associated product lists current would require updates on a weekly, if not daily, basis. With the procedures envisioned and the anticipated frequency of updates, the Commission concluded that it would incur prohibitive publication costs and challenging resource burdens.<sup>4</sup>

In the interim, the Postal Service and the Commission each maintained versions of the MCS. The Postal Service used its version when presenting price and classification proposals to the Commission for evaluation. This required the Commission to first resolve any differences between the Commission's version of the MCS and the Postal Service's version of the MCS before considering the Postal Service's proposals.

On April 1, 2013, the Commission published its version of the MCS to the Commission's Web site.<sup>5</sup> This provided visibility to all interested persons participating in Commission proceedings as to current prices and classifications. From this point forward, the Postal Service submitted its proposed price and classification changes based on this version of the MCS.

The Commission developed internal procedures for updating the draft MCS appearing on its Web site on approximately a monthly basis. The Commission displays all changes in redline, as had been requested by the Postal Service. The redline changes are incorporated, and a new baseline MCS created, at the conclusion of major price or classification proceedings. All prior versions of the MCS are archived and available on the Web site for reference.

<sup>4</sup> The Commission also explored a "publication by reference" approach with the **Federal Register**. This approach presented an equal number of challenges to the Commission and was dropped from consideration.

<sup>5</sup> Notice of Posting Draft Mail Classification Schedule to the Commission's Web site, April 1, 2013. At this stage in the development of the MCS, the Commission's version and the Postal Service's version were nearly identical.

The Commission also developed internal procedures for publishing product list changes in the **Federal Register** and for updating the outline MCS appearing in the CFR. The Commission, at that time, removed the table of contents from the outline MCS and simply provided current market dominant and competitive product lists.<sup>6</sup> The Commission also elected to notice product list changes in the **Federal Register** and update the product lists in the CFR on approximately a quarterly basis. Internal Commission procedures were implemented to compile product list changes directed by Commission orders by calendar quarter. The compiled list of changes are noticed in the **Federal Register** and are used to update the outline MCS appearing in the CFR shortly after the close of each calendar quarter.

The instant rulemaking proposes to codify the current practice, as described in the above procedures. The MCS appearing on the Web site has proven effective in documenting current prices and classifications and in facilitating communications of the Postal Service's proposed price and classification changes to the Commission. The procedures for noticing product list changes in the **Federal Register** and updating product lists in the CFR fulfill the statutory requirements for publishing revised product lists.

The effect of the rulemaking is to make the version of the MCS appearing on the Commission's Web site the authoritative and most up to date comprehensive source for price and classification information for Postal Service products.<sup>7</sup> In keeping with current practice, the proposed rules codify that product lists will continue to be published in the CFR, with notice of changes published in the **Federal Register**. The proposed rules no longer indicate that the MCS will be published in the CFR.

### III. Rule Modifications

The Commission's existing rules concerning the MCS, which include the associated market dominant and the competitive product lists, are codified at 39 CFR part 3020, subpart A—Mail Classification Schedule. An abridged version of the MCS (which only includes the market dominant and competitive product lists) is codified at

39 CFR part 3020, Appendix A to subpart A—Mail Classification Schedule.

This rulemaking codifies current practice. The product lists and the MCS will be treated as separate items. Only the product lists are noticed in the **Federal Register** and published in the CFR. The MCS will be available on the Commission's Web site.<sup>8</sup> Conforming changes are also required in 39 CFR part 3020, subparts B, C, and D.

The title of subpart A is changed from "Mail Classification Schedule" to "Product Lists and Mail Classification Schedule." The addition of "Product Lists" to the title more accurately describes the content of subpart A.

The existing § 3020.1, "Applicability," specifies that the market dominant and competitive product lists are to be included as part of the MCS. The proposed § 3020.1 describes the product lists and the MCS as separate items.

Proposed § 3020.1(a) clarifies that it is the Commission's responsibility to establish and maintain lists of Postal Service products and a MCS.

Proposed § 3020.1(b) replaces existing § 3020.1(a). Both specify that the starting point for the product lists are the market dominant products identified in 39 U.S.C. 3621(a) and the competitive products identified in 39 U.S.C. 3631(a). Proposed § 3020.1(b) expands upon this requirement by including products within the product lists identified as market tests pursuant to 39 U.S.C. 3641 and nonpostal pursuant to 39 U.S.C. 404(e). This flows from the requirement for the Postal Service to properly categorize market tests as either market dominant or competitive (39 U.S.C. 3641(b)(2)) and the Commission to properly categorize nonpostal services as either market dominant or competitive (39 U.S.C. 404(e)(5)).<sup>9</sup>

Proposed § 3020.1(c) states the purpose of the MCS as providing current price and classification information applicable to the products appearing on the market dominant and competitive product lists.

Proposed § 3020.1(d) modifies the material previously included in existing § 3020.1(b) by addressing the product lists and the MCS as two separate items. The proposed section provides that

either item may be modified subject to the procedures in 39 CFR part 3020.

Proposed § 3020.2 directs that the market dominant and competitive product lists shall be published in the **Federal Register** as appendix A to subpart A of part 3020 and appendix B to subpart A of part 3020, respectively. Currently, an abridged version of the MCS, which includes only the market dominant and competitive product lists, is published in the **Federal Register** as appendix A to subpart A of part 3020. The intent of the existing rule was to eventually publish the entire MCS in the **Federal Register**. The intent of the proposed rule is to implement current practice and only publish the market dominant and competitive product lists in the **Federal Register**. Providing a separate appendix for each product list is intended to potentially reduce **Federal Register** publication costs when modifications are required of one product list but not the other.

Proposed § 3020.3 explains how product lists are modified and how the public is notified of such changes. This section replaces and expands upon the material previously appearing in existing § 3020.14. Generally, § 3020.3 implements the publication requirement appearing in 39 U.S.C. 3642(d)(2), which requires **Federal Register** notice of product list changes.

Proposed § 3020.3(a) explains that the requirement to publish notice of a product list change is triggered by a Commission final order that directs such changes.

The current practice of the Commission is to accumulate all final orders involving changes to product lists and to file a product list update with the **Federal Register** on a quarterly basis. Proposed § 3020.3(b) sets a maximum 6-month deadline for filing the quarterly update. This essentially provides a maximum of 3 months from the quarterly accumulation cutoff date to process and submit the changes to the **Federal Register**.

The Commission's position is that Commission orders issued within its jurisdiction are binding upon the Postal Service when issued, unless challenged pursuant to 39 U.S.C. 3663.

Accordingly, § 3020.3(c) specifies that changes to product lists are effective upon issuance of the final order, and not upon publication in the **Federal Register**, which generally occurs at a later date.

Proposed § 3020.3(d) specifies the content of the **Federal Register** notice consistent with the requirements of 39 U.S.C. 3642(d)(2). This material previously appeared in existing § 3020.14.

<sup>6</sup> The table of contents was hopelessly outdated and contradicted the table of contents appearing in the MCS appearing on the Commission's Web site.

<sup>7</sup> The proposed rules recognize the immediate binding effect of the Commission's final orders on the Postal Service, subject to statutory challenge, and the inherent time lag in updating product lists and the MCS.

<sup>8</sup> For the convenience of the reader, the MCS will include copies of the market dominant and competitive product lists.

<sup>9</sup> This change was adopted at the suggestion of the Docket No. RM2011-8 Public Representative. Docket No. RM2011-8, Public Representative Comments on Notice of Proposed Rulemaking Concerning Mail Classification Schedule, March 24, 2011, at 5.

Since April 1, 2013, the MCS has been available on the Commission's Web site at [www.prc.gov](http://www.prc.gov). Proposed § 3020.4(a) directs the Commission to publish the authoritative version of the MCS on its Web site. Proposed § 3020.4(b) describes the minimum required content of the MCS. This material previously appeared in existing § 3020.13.

Proposed § 3020.5 explains that modifications to the MCS are triggered by Commission final orders directing such changes.

The current practice of the Commission is to accumulate all final orders involving changes to the MCS and to update it on a monthly basis. Proposed § 3020.5(b) sets a maximum 3-month deadline for filing the quarterly update. This essentially provides a maximum of 2 months from the quarterly accumulation cutoff date to process and post a revised MCS to the Web site.

The Commission's position is that its orders are binding upon the Postal Service when issued, unless challenged pursuant to 39 U.S.C. 3663. Accordingly, § 3020.3(c) specifies that changes to the MCS are effective upon issuance of the final order, and not once the MCS is actually modified, which generally occurs at a later date.

The titles to 39 CFR part 3020, subparts B, C, and D and §§ 3020.30, 3020.50, and 3020.70 refer to the product lists as being within the MCS. Conforming changes are proposed to remove this reference.

#### IV. Public Representative

Pursuant to 39 U.S.C. 505, Kenneth E. Richardson is appointed to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this docket.

#### V. Invitation of Comments

The Commission invites public comment on the proposed rules. Comments by interested persons are due 30 days after publication in the **Federal Register**.

#### VI. Ordering Paragraphs

*It is ordered:*

1. Docket No. RM2016-8 is established for the purpose of receiving comments on the Commission's proposed rules.

2. The Commission proposes to amend its rules as described below. The proposed amendments involve amending 39 CFR part 3020, subpart A—Mail Classification Schedule, and conforming amendments to subparts B, C, and D.

3. Pursuant to 39 U.S.C. 505, the Commission appoints Kenneth E. Richardson to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

4. Interested persons may submit comments no later than 30 days after the date of publication of this Order in the **Federal Register**.

5. The Secretary shall arrange for publication of this Order in the **Federal Register**.

By the Commission.

**Stacy L. Ruble**,  
Secretary.

#### List of Subjects in 39 CFR Part 3017

Administrative practice and procedure.

For the reasons discussed in the preamble, the Commission proposes to amend chapter III of title 39 of the Code of Federal Regulations as follows:

#### PART 3020—PRODUCT LISTS

■ 1. The authority citation for part 3020 continues to read as follows:

**Authority:** 39 U.S.C. 503; 3622; 3631; 3642; 3682.

■ 2. Revise subpart A of part 3020 to read as follows:

#### Subpart A—Product Lists and the Mail Classification Schedule

Sec.

3020.1 Applicability.

3020.2 Product lists.

3020.3 Notice of product list change.

3020.4 Mail Classification Schedule.

3020.5 Modifications to the Mail Classification Schedule.

Appendix A to Subpart A of Part 3020—  
Market Dominant Product List

Appendix B to Subpart A of Part 3020—  
Competitive Product List

#### § 3020.1 Applicability.

(a) The rules in this part require the Postal Regulatory Commission to establish and maintain lists of Postal Service products and a Mail Classification Schedule.

(b) The product lists shall categorize postal products as either market dominant or competitive. As established, the market dominant and competitive product lists—shall be consistent with the market dominant products identified in 39 U.S.C. 3621(a) and the competitive products identified in 39 U.S.C. 3631(a). The market dominant and competitive product lists shall also include products identified as market tests pursuant to 39 U.S.C. 3641 and nonpostal pursuant to 39 U.S.C. 404(e).

(c) The Mail Classification Schedule shall provide current price and classification information applicable to the products appearing on the market dominant and competitive product lists.

(d) Once established, the product lists and the Mail Classification Schedule may be modified subject to the procedures specified in this part.

#### § 3020.2 Product lists.

(a) *Market dominant product list.* The market dominant product list shall be published in the **Federal Register** at Appendix A to subpart A of part 3020—Market Dominant Product List.

(b) *Competitive product list.* The competitive product list shall be published in the **Federal Register** at Appendix B to subpart A of part 3020—Competitive Product List.

#### § 3020.3 Notice of product list change.

(a) Whenever the Postal Regulatory Commission issues a final order that modifies the list of products in the market dominant category or the competitive category, it shall cause notice of such change to be published in the **Federal Register**.

(b) Notice shall be submitted to the **Federal Register** for publication within 6 months of the issue date of the applicable final order that affects the change.

(c) Modifications pending publication in the **Federal Register** are effective immediately upon written direction from the Postal Regulatory Commission.

(d) The **Federal Register** notice shall:

(i) Identify modifications to the current list of market dominant products and the current list of competitive products; and

(ii) Indicate how and when the previous product lists have been modified.

#### § 3020.4 Mail Classification Schedule.

(a) The Postal Regulatory Commission shall publish a Mail Classification Schedule (including both current and previous versions) on its Web site at <http://www.prc.gov>. Copies of the Mail Classification Schedule also shall be available during regular business hours for reference and public inspection at the Postal Regulatory Commission located at 901 New York Avenue NW., Suite 200, Washington, DC 20268-0001.

(b) The Mail Classification Schedule shall include, but shall not be limited to: (1) Front matter, including:

(i) A cover page identifying the title of the document as the Mail Classification Schedule, the source of the document as the Postal Regulatory Commission (including Commission seal), and the publication date;

- (ii) A table of contents;
- (iii) A table specifying the revision history of the Mail Classification Schedule; and
- (iv) A table identifying Postal Service trademarks; and
- (2) Information concerning market dominant products, including:
  - (i) A copy of the Market Dominant Product List;
  - (ii) Descriptions of each market dominant product organized by the class of product, including:
    - (A) Where applicable, the general characteristics, size and weight limitations, minimum volume requirements, price categories, and available optional features of each market dominant product;
    - (B) A schedule listing the rates and fees for each market dominant product;
    - (C) Where applicable, the identification of a product as a special classification within the meaning of 39 U.S.C. 3622(c)(10) for market dominant products;
    - (D) Where applicable, the identification of a product as an experimental product undergoing a market test; and
    - (E) Where applicable, the identification of a product as a nonpostal product; and
  - (3) Information concerning competitive products, including:
    - (i) A copy of the competitive product list; and
    - (ii) Descriptions of each competitive product, including:
      - (A) Where applicable, the general characteristics, size and weight limitations, minimum volume requirements, price categories, and available optional features of each competitive product;
      - (B) A schedule listing the current rates and fees for each competitive product of general applicability;
      - (C) The identification of each product not of general applicability within the meaning of 39 U.S.C. 3632(b)(3) for competitive products;
      - (D) Where applicable, the identification of a product as an experimental product undergoing a market test; and
      - (E) Where applicable, the identification of a product as a nonpostal product; and
    - (4) A glossary of terms and conditions; and
    - (5) A list of country codes for international mail prices.

**§ 3020.5 Modifications to the Mail Classification Schedule.**

(a) Whenever the Postal Regulatory Commission issues a final order that modifies the Mail Classification

Schedule, it shall update the Mail Classification Schedule appearing on its Web site at <http://www.prc.gov>.

- (b) Modification to the Mail Classification Schedule shall be incorporated within 3 months of the issue date of the final order.
- (c) Modifications pending incorporation into the Mail Classification Schedule are effective immediately upon written direction from the Postal Regulatory Commission.

**Appendix A to Subpart A of Part 3020—Market Dominant Product List**

(An asterisk (\*) indicates an organizational group, not a Postal Service product.)

- First-Class Mail \*
  - Single-Piece Letters/Postcards
  - Presorted Letters/Postcards
  - Flats
  - Parcels
  - Outbound Single-Piece First-Class Mail
  - International
  - Inbound Letter Post
  - Standard Mail (Commercial and Nonprofit) \*
    - High Density and Saturation Letters
    - High Density and Saturation Flats/Parcels
    - Carrier Route
    - Letters
    - Flats
    - Parcels
    - Every Door Direct Mail—Retail
  - Periodicals \*
    - In-County Periodicals
    - Outside County Periodicals
  - Package Services \*
    - Alaska Bypass Service
    - Bound Printed Matter Flats
    - Bound Printed Matter Parcels
    - Media Mail/Library Mail
  - Special Services \*
    - Ancillary Services
    - International Ancillary Services
    - Address Management Services
    - Caller Service
    - Credit Card Authentication
    - International Reply Coupon Service
    - International Business Reply Mail Service
    - Money Orders
    - Post Office Box Service
    - Customized Postage
    - Stamp Fulfillment Services
  - Negotiated Service Agreements \*
    - Domestic \*
      - PHI Acquisitions, Inc. Negotiated Service Agreement
    - International \*
      - Inbound Market Dominant Multi-Service Agreements with Foreign Postal Operators 1
      - Inbound Market Dominant Exprés Service Agreement 1
  - Nonpostal Services \*
    - Alliances with the Private Sector to Defray Cost of Key Postal Functions
    - Philatelic Sales
  - Market Tests \*

**Appendix B to Subpart A of Part 3020—Competitive Product List**

(An asterisk (\*) indicates an organizational class or group, not a Postal Service product.)

- Domestic Products \*
  - Priority Mail Express
  - Priority Mail
  - Parcel Select
  - Parcel Return Service
  - First-Class Package Service
  - Retail Ground
- International Products \*
  - Outbound International Expedited Services
  - Inbound Parcel Post (at UPU rates)
  - Outbound Priority Mail International
  - International Priority Airmail (IPA)
  - International Surface Air List (ISAL)
  - International Direct Sacks—M-Bags
  - Outbound Single-Piece First-Class Package International Service
- Negotiated Service Agreements \*
  - Domestic \*
    - Priority Mail Express Contract 8
    - Priority Mail Express Contract 15
    - Priority Mail Express Contract 16
    - Priority Mail Express Contract 17
    - Priority Mail Express Contract 18
    - Priority Mail Express Contract 19
    - Priority Mail Express Contract 20
    - Priority Mail Express Contract 21
    - Priority Mail Express Contract 22
    - Priority Mail Express Contract 23
    - Priority Mail Express Contract 24
    - Priority Mail Express Contract 25
    - Priority Mail Express Contract 26
    - Priority Mail Express Contract 27
    - Priority Mail Express Contract 28
    - Priority Mail Express Contract 29
    - Priority Mail Express Contract 30
    - Priority Mail Express Contract 31
    - Priority Mail Express Contract 32
    - Priority Mail Express Contract 33
    - Priority Mail Express Contract 34
    - Priority Mail Express Contract 35
    - Parcel Return Service Contract 5
    - Parcel Return Service Contract 6
    - Parcel Return Service Contract 7
    - Parcel Return Service Contract 8
    - Parcel Return Service Contract 9
    - Parcel Return Service Contract 10
    - Priority Mail Contract 24
    - Priority Mail Contract 29
    - Priority Mail Contract 33
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    - Priority Mail Contract 58
    - Priority Mail Contract 59
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GEPS 3  
 Global Bulk Economy (GBE) Contracts  
 Global Plus Contracts  
 Global Plus 1C  
 Global Plus 2C  
 Global Reseller Expedited Package  
 Contracts  
 Global Reseller Expedited Package Services  
 1  
 Global Reseller Expedited Package Services  
 2  
 Global Reseller Expedited Package Services  
 3  
 Global Reseller Expedited Package Services  
 4  
 Global Expedited Package Services  
 (GEPS)—Non-Published Rates  
 Global Expedited Package Services  
 (GEPS)—Non-Published Rates 2  
 Global Expedited Package Services  
 (GEPS)—Non-Published Rates 3  
 Global Expedited Package Services  
 (GEPS)—Non-Published Rates 4  
 Global Expedited Package Services  
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 Global Expedited Package Services  
 (GEPS)—Non-Published Rates 6  
 Global Expedited Package Services  
 (GEPS)—Non-Published Rates 7  
 Global Expedited Package Services  
 (GEPS)—Non-Published Rates 8  
 Global Expedited Package Services  
 (GEPS)—Non-Published Rates 9  
 Global Expedited Package Services  
 (GEPS)—Non-Published Rates 10  
 Priority Mail International Regional Rate  
 Boxes—Non-Published Rates  
 Outbound Competitive International  
 Merchandise Return Service Agreement  
 with Royal Mail Group, Ltd.  
 Priority Mail International Regional Rate  
 Boxes Contracts  
 Priority Mail International Regional Rate  
 Boxes Contracts 1  
 Competitive International Merchandise  
 Return Service Agreements with Foreign  
 Postal Operators  
 Competitive International Merchandise  
 Return Service Agreements with Foreign  
 Postal Operators 1  
 Competitive International Merchandise  
 Return Service Agreements with Foreign  
 Postal Operators 2  
 Inbound International \*  
 International Business Reply Service  
 (IBRS) Competitive Contracts  
 International Business Reply Service  
 Competitive Contract 1  
 International Business Reply Service  
 Competitive Contract 3  
 Inbound Direct Entry Contracts with  
 Customers  
 Inbound Direct Entry Contracts with  
 Foreign Postal Administrations  
 Inbound Direct Entry Contracts with  
 Foreign Postal Administrations  
 Inbound Direct Entry Contracts with  
 Foreign Postal Administrations 1  
 Inbound EMS  
 Inbound EMS 2  
 Inbound Air Parcel Post (at non-UPU rates)  
 Royal Mail Group Inbound Air Parcel Post  
 Agreement  
 Inbound Competitive Multi-Service  
 Agreements with Foreign Postal  
 Operators 1

Special Services \*  
 Address Enhancement Services  
 Greeting Cards, Gift Cards, and Stationery  
 International Ancillary Services  
 International Money Transfer Service—  
 Outbound  
 International Money Transfer Service—  
 Inbound  
 Premium Forwarding Service  
 Shipping and Mailing Supplies  
 Post Office Box Service  
 Competitive Ancillary Services  
 Nonpostal Services \*  
 Advertising  
 Licensing of Intellectual Property other  
 than Officially Licensed Retail Products  
 (OLRP)  
 Mail Service Promotion  
 Officially Licensed Retail Products (OLRP)  
 Passport Photo Service  
 Photocopying Service  
 Rental, Leasing, Licensing or other Non-  
 Sale Disposition of Tangible Property  
 Training Facilities and Related Services  
 USPS Electronic Postmark (EPM) Program  
 Market Tests \*  
 International Merchandise Return Service  
 (IMRS)—Non-Published Rates  
 Customized Delivery

#### Subpart B—Requests Initiated by the Postal Service To Modify the Product Lists

- 3. Revise the heading of subpart B to read as set forth above.
- 4. Revise § 3020.30 to read as follows:

#### § 3020.30 General.

The Postal Service, by filing a request with the Commission, may propose a modification to the market dominant product list or the competitive product list. For purposes of this part, modification shall be defined as adding a product to a list, removing a product from a list, or moving a product from one list to the other list.

#### Subpart C—Requests Initiated by Users of the Mail To Modify the Product Lists

- 5. Revise the heading of subpart C as set forth above.
- 6. Revise § 3020.50 to read as follows:

#### § 3020.50 General.

Users of the mail, by filing a request with the Commission, may propose a modification to the market dominant product list or the competitive product list. For purposes of this part, modification shall be defined as adding a product to a list, removing a product from a list, or transferring a product from one list to the other list.

#### Subpart D—Proposal of the Commission To Modify the Product Lists

- 7. Revise the heading of subpart D as set forth above.

#### Subpart D—Proposal of the Commission To Modify the Product Lists

- 8. Revise § 3020.70 to read as follows:

#### § 3020.70 General.

The Commission, of its own initiative, may propose a modification to the market dominant product list or the competitive product list. For purposes of this part, modification shall be defined as adding a product to a list, removing a product from a list, or transferring a product from one list to the other list.

[FR Doc. 2016-08322 Filed 4-11-16; 8:45 am]

BILLING CODE 7710-FW-P

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 65

[WC Docket Nos. 10–90, 14–58; CC Docket No. 01–92; FCC 16–33]

#### Connect America Fund, ETC Annual Reports and Certification; Developing a Unified Inter-carrier Compensation Regime

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** In this document, the Federal Communications Commission (Commission) proposes targeted rule changes to our existing accounting and affiliate transaction rules to eliminate inefficiencies and provide guidance to rate-of-return carriers regarding our expectations for appropriate expenditures.

**DATES:** Comments are due on or before May 12, 2016 and reply comments are due on or before June 13, 2016. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this document, you should advise the contact listed below as soon as possible.

**ADDRESSES:** You may submit comments, identified by either WC Docket No. 10–90, WC Docket No. 14–58 or CC Docket No. 01–92, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Federal Communications Commission's Web site:* <http://fjallfoss.fcc.gov/ecfs2/>. 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](mailto: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:**

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**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Further Notice of Proposed Rulemaking (FNPRM) in WC Docket Nos. 10-90, 14-58 and CC Docket No. 01-92; FCC 16-33, adopted on March 23, 2016 and released on March 30, 2016. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY-A257, 445 12th St. SW., Washington, DC 20554 or at the following Internet address: [http://transition.fcc.gov/Daily\\_Releases/Daily\\_Business/2016/db0330/FCC-16-33A1.pdf](http://transition.fcc.gov/Daily_Releases/Daily_Business/2016/db0330/FCC-16-33A1.pdf). The Report and Order, Order and Order on Reconsideration that was adopted concurrently with the FNPRM are published elsewhere in this issue of the **Federal Register**.

**I. Introduction**

1. With this Further Notice of Proposed Rulemaking (FNPRM) and concurrently adopted Report and Order, Order, Order on Reconsideration, the Commission adopts significant reforms to place the universal service program on solid footing for the next decade to "preserve and advance" voice and broadband service in areas served by rate-of-return carriers. In 2011, the Commission unanimously adopted transformational reforms to modernize universal service for the 21st century, creating programs to support explicitly broadband-capable networks. In this Report and Order, Order, Order on Reconsideration, and FNPRM, the Commission takes necessary and crucial steps to reform our rate-of-return universal service mechanisms to fulfill our statutory mandate of ensuring that all consumers "have access to . . . advanced telecommunications and information services." In particular, after extensive coordination and engagement with carriers and their associations, the Commission modernizes the rate-of-return program to support the types of broadband offerings that consumers increasingly demand, efficiently target support to areas that need it the most, and establish

concrete deployment obligations to ensure demonstrable progress in connecting unserved consumers. This will provide the certainty and stability that carriers seek in order to invest for the future in the years to come. The Commission welcomes ongoing input and partnership as they move forward to implementing these reforms.

2. Rate-of-return carriers play a vital role in the high-cost universal service program. Many of them have made great strides in deploying 21st century networks in their service territories, in spite of the technological and marketplace challenges to serving some of the most rural and remote areas of the country. At the same time, millions of rural Americans remain unserved. In 2011, the Commission unanimously concluded that extending broadband service to those communities that lacked any service was one of core objectives of reform. At that time, it identified a rural-rural divide, observing that "some parts of rural America are connected to state-of-the art broadband, while other parts of rural America have no broadband access." The Commission focuses now on the rural divide that exists within areas served by rate-of-return carriers. According to December 2014 Form 477 data, an estimated 20 percent of the housing units in areas served by rate-of-return carriers lack access to 10 Mbps downstream/1 Mbps upstream (10/1 Mbps) terrestrial fixed broadband service. It is time to close the gap, and take action to bring service to the consumers served by rate-of-return carriers that lack access to broadband. The Commission needs to modernize comprehensively the rate-of-return universal service program in order to benefit rural consumers throughout the country.

3. For years, the Commission has worked with active engagement from a wide range of interested stakeholders to develop new rules to support broadband-capable networks. One shortcoming of the current high-cost rules identified by rate-of-return carriers is that support is not provided if consumers choose to drop voice service, often referred to as "stand-alone broadband" or "broadband-only" lines. In the *April 2014 Connect America FNPRM*, 79 FR 39196, July 9, 2014, the Commission unanimously articulated four general principles for reform to address this problem, indicating that new rules should provide support within the established budget for areas served by rate-of-return carriers; distribute support equitably and efficiently, so that all rate-of-return carriers have the opportunity to extend broadband service where it is cost-

effective to do so; support broadband-capable networks in a manner that is forward looking; and ensure no double-recovery of costs. The package of reforms outlined below solve the stand-alone broadband issue and update the rate-of-return program consistent with those principles. The Commission also takes important steps to act on the recommendation of the Governmental Accountability Office to ensure greater accountability and transparency in the high-cost program.

4. In the FNPRM, the Commission proposes targeted rule changes to our existing accounting and affiliate transaction rules to eliminate inefficiencies and provide guidance to rate-of-return carriers regarding our expectations for appropriate expenditures. Consumers are harmed when "universal service provides more support than necessary to achieve our goals." The statute requires that universal service funds be used for their intended purposes—maintaining and upgrading supported facilities and services. The Commission proposes to eliminate a number of expenses from inclusion in a rate-of-return carrier's revenue requirement and calculations of high-cost support. The Commission also seeks comment on establishing measures governing prudent or reasonable expense levels for certain expense categories. The FNPRM further seeks comment on ways in which the cost allocation procedures between regulated and non-regulated activities and the affiliate transaction rules can be improved to reduce the potential for a carrier to shift costs from non-regulated to regulated services or to the regulated affiliate.

5. Second, the Commission seeks comment in the FNPRM on additional options for disaggregating support for those discrete areas that are served by an unsubsidized competitor and other issues associated with implementation of the competitive overlap rule.

6. Third, the FNPRM seeks comment on proposals to adopt a mechanism to provide additional support to unserved Tribal lands. The Commission has long recognized the distinct challenges in bringing communications service to Tribal lands.

7. Fourth, the FNPRM seeks comment on other measures that the Commission could take within the existing budget to encourage further broadband deployment by rate-of-return carriers.

8. Lastly, the FNPRM seeks comment on additional proposals to modify or potentially eliminate certain eligible telecommunications carriers' (ETC) certifications and reporting obligations

so as to streamline ETC reporting requirements.

9. The actions the Commission takes today, combined with the rate-of-return reforms undertaken in the past two years, will allow us to continue to advance the goal of ensuring deployment of advanced telecommunications and information services networks throughout “all regions of the nation.” Importantly, they build on proposals from and collaboration with the carriers and their associations. Through the coordinated reforms the Commission takes today, they will provide rate-of-return carriers with equitable and sustainable support for investment in the deployment and operation of 21st century broadband networks throughout the country, providing stability for the future. Achieving universal access to broadband will not occur overnight, but today marks another step on the path toward that goal.

## II. Further Notice of Proposed Rulemaking

### A. Permitted Expenses, Cost Allocation and Affiliate Transactions

10. With this Notice, the Commission commences a review of the extent to which certain investments and expenses incurred by a regulated local exchange carrier may be included in its rate base and revenue requirement for ratemaking and universal service fund (USF) purposes. The Commission’s rules provide that local exchange carriers may not include expenses in their revenue requirement unless such expenses are “recognized by the Commission as necessary to the provision” of interstate telecommunications services. Similarly, high-cost support provided to an ETC must be used “only for the provision, maintenance, and upgrading of facilities and services for which the support is intended.”

11. The Commission has not comprehensively reviewed the continued reasonableness of its existing rules regarding permissible investments and expenses for local exchange carriers since the passage of the Telecommunications Act of 1996. Market and regulatory conditions have changed substantially since that time. Notably, regulated telecommunications carriers have expanded into the provision of retail broadband services, either directly or through affiliated entities. Regulated carriers also increasingly face competition, for both voice and broadband services, in portions of their incumbent territory from other facilities-based providers, such as cable and wireless providers.

These changing conditions may impact the types of costs carriers attempt to include in their revenue requirement and the ways in which carriers allocate costs between regulated and non-regulated services and affiliates.

12. Moreover, with steady demands on the high-cost program and a shrinking contribution base, it is more important than ever that these limited funds be used solely for their intended purposes. Likewise, amidst challenging economic conditions, it simply is not right to expect consumers across the country, including those in rural areas, to reimburse rate-of-return carriers—through the regulated rates for interstate service—for excessive or otherwise inappropriate expenses.

13. While the Commission believes that most rate-of-return carriers properly record their costs and seek support only for the intended purposes, through audits, inquiries and other investigations, the Commission has recently been made aware of alleged abuses by rate-of-return carriers of the used and useful principles and its cost allocation rules. These situations involve rate-of-return carriers, for example, including questionable expenses in their revenue requirement, using support for purposes unrelated to the provision of services, and misallocating expenses among affiliates, or between regulated and non-regulated activities. Against that backdrop, the Commission concludes it is time to reevaluate the types of expenses that should be permitted—both in a carrier’s revenue requirement and for recovery through high-cost support. Looking into the expenses permitted and the allocation of those expenses will help ensure that carriers are only recovering costs that are used and useful and prudently incurred, and in the case of high cost support, only costs that are necessary to the provision of interstate telecommunications services.

#### 1. Discussion

##### a. Review of Permitted Expenses

14. The Commission begins our reevaluation of a rate-of-return carrier’s ability to include certain types of expenses in their revenue requirement and high-cost support with consideration of the appropriate standard to be applied. As noted above, the Commission has used different terms in different situations—“used and useful,” “prudent expenditure,” and “necessary to the provision of.” The Commission believes that these terms should be read consistently to describe those expenses that a carrier may appropriately include in its interstate

rate base, interstate revenue requirement, and cost studies used to calculate high-cost support. Thus, they should reflect a business operation that is run efficiently to provide telecommunications services. The costs should include amounts of long-term investment and current expenditures that a business would reasonably incur to provide telecommunications services, taking into account current and reasonably forecasted operating conditions and business levels. The Commission invites parties to comment on these standards and whether they should be viewed as applying a consistent standard to regulated, tariffed services and to expenditures that are recovered through high-cost support. To the extent that a party believes different standards should be applied, it should specify the situations in which such differences should apply, what the differences are, and how they should be treated within the accounting and cost allocation processes of the Commission. As parties respond to the issues raised below, they should consider the application of the standards in their comments.

15. The Commission recently indicated that ETCs may not recover certain types of expenses through high-cost support. Those expenses include the following: Personal travel; entertainment; alcohol; food, including but not limited to meals to celebrate personal events, such as weddings, births, or retirements; political contributions; charitable donations; scholarships; penalties or fines for statutory or regulatory violations; penalties or fees for any late payments on debt, loans, or other payments; membership fees and dues in clubs and organizations; sponsorships of conferences or community events; gifts to employees; and, personal expenses of employees, board members, family members of employees and board members, contractors, or any other individuals affiliated with the ETC, including but not limited to personal expenses for housing, such as rent or mortgages.

16. The Commission seeks comment on explicitly prohibiting the inclusion of any of these expenses in a carrier’s interstate revenue requirement, which would supersede any existing rules or precedent that might otherwise suggest these are legitimate expenditures. The Commission tentatively concludes that these expenditures are unnecessary to the provision of regulated interstate services and thus are not appropriately included in a rate-of-return carrier’s interstate revenue requirement, just as they are not appropriately included in



calculating the level of high-cost support a carrier receives. Recognizing that some of these enumerated types of expenditures are quite broad, however, the Commission invites parties to indicate whether there is a definable subset of expenses within any of the categories that should not be excluded from a carrier's interstate revenue requirement. Parties believing there are specific types of expenses that should be included in the interstate revenue requirement should provide examples of such expenses, the reasons they are necessary, as well as specific language that would allow the Commission to distinguish these expenses from those that are appropriately excluded. The Commission also seeks comment on whether, if the Commission ultimately decides some of these expense categories, or a portion of them, should be allowed in a carrier's interstate revenue requirement, whether similar treatment should be accorded those expenses for purposes of high-cost support.

17. In addition to the expenses identified in the *High Cost Oct. 19, 2015 Public Notice*, the Commission proposes to prohibit additional expenses from inclusion in a carrier's interstate revenue requirement and also preclude their recovery through high-cost support. The additional expenses that the Commission proposes to disallow for these purposes include: Artwork and other objects which possess aesthetic value; corporate aircraft, watercraft, and other motor vehicles designed for off-road use, except insofar as necessary to access inhabited portions of the study area not reachable by motor vehicles travelling on roads; any vehicles for personal use; tangible property not logically related or necessary to the offering of voice or broadband services; childcare; cafeterias and dining facilities; and, housing allowances or other forms of mortgage or rent assistance for employees. Like the expenses listed above, the Commission is concerned that some carriers may incur additional expenses of this nature that are not necessary to the provision of the supported service—voice telephony—and not necessary to the provision of regulated interstate services. If adopted, such a rule would overturn any existing rule or precedent that might suggest such expenditures are permissible.

18. The Commission invites parties to comment on whether there is any reason that these expense categories should not be completely excluded from a carrier's revenue requirement or its high-cost support. Parties making an argument for inclusion of these expenses in a carrier's

revenue requirement should explain clearly why such expenses are necessary to the provision of a supported service or to the provision of a regulated interstate telecommunications service. The Commission invites parties to indicate whether there is a definable subset of expenses within any of the categories that should not be excluded from a carrier's interstate revenue requirement or high-cost support. Parties believing that to be the case should provide examples of such expenses, the reason they are necessary, as well as specific language that would allow the Commission to distinguish these expenses from those that are appropriately excluded.

19. The Commission also invites parties to identify additional expenses that should be excluded from either a carrier's interstate revenue requirement, from calculations of high-cost support, or both. Parties identifying additional expenses to be excluded should address the reasons they are unnecessary to the provision of telecommunications service or to the provision of supported services. Parties seeking additional exclusions should also provide language that would allow the Commission to exclude such items if it elects to do so. With respect to ensuring the appropriate use of high-cost funds for certain expenses, our proposals apply to both price cap and rate-of-return carriers. Our proposals concerning permitted expenses for the revenue requirement would primarily apply to rate-of-return carriers, but they would also apply to price cap carriers in limited circumstances.

20. In addition to these categories, the Commission has seen instances in which "companies maintain comparatively high compensation portfolios for their executives." The Commission expressed concern that these and other expenses were not reasonable and necessary given a number of considerations. The Commission seeks comment on how to address potential concerns regarding such expenses for executives, those with close relationships to those executives, and a carrier's other employees and contractors.

21. The Commission is also aware of at least one instance in which costly benefits were sought to be provided to board members. Are there circumstances under which compensation for board members, including fees per-meeting, for special duties assumed, and for travel and per diem expenses should be deemed unreasonable? If so, on what basis? Is additional evaluation warranted where board members have a close

relationship to someone in the company?

22. The Commission seeks comment on whether the costs that may be included in a carrier's revenue requirement for buildings purchased or rented by regulated telecommunications carriers should be limited. For example, in cases where excessive square footage of office or warehouse space is purchased by a regulated carrier in order to earn a rate of return on that space, should part of the price paid for the building be excluded from the revenue requirement? How should "excessive" be defined for this purpose? Are there objective metrics available on the square footage of office space per employee that is reasonable, or on the square footage of warehouse space that a carrier should reasonably require given the number of loops the carrier provides and the density of its service area? Are there objective metrics on the price per square foot that should be paid for office or warehouse space in specific locations?

23. Section 32.2002 provides that plant held for future use must be utilized within two years. This plant is included in the carrier's rate base. The Commission is concerned that carriers may have incentives to place excess capacity in the interstate regulated rate base that will not be used in the foreseeable future, with ratepayers bearing the cost. The Commission reminds carriers that the benefit from a used and useful investment must be realized within a reasonable amount of time. Thus, the Commission invites parties to comment on whether they should adopt a rule that would prohibit a regulated carrier from leasing capacity from its unregulated affiliate that is not presently utilized in the provision of voice or broadband services. Alternatively, could this concern be addressed by defining more precisely what constitutes reasonable projections of use and/or requiring that such capacity be used within a shorter timeframe than two years? Parties are invited to address the types of uses that should be considered to meet the requirement that excess capacity be used in the foreseeable future.

24. As explained above, carriers record their financial transactions in the USOA books of account as they occur. These amounts then flow through the allocation procedures in Parts 64, 36, and 69 with the implied assumption that the recorded amounts are reasonable, and thus prudently incurred. While the used and useful and prudent expenditure standards apply to all investments and expenses of the carrier, the principles considered under

this standard have been interpreted only in limited, specific cases. The Commission now seeks comment on whether the Commission should adopt more precise guidance regarding what constitutes a used and useful or otherwise prudent expenditure.

25. The Commission notes that transactions between non-affiliated parties that are negotiated at arm's length are generally presumed to produce commercially reasonable prices. Affiliate transactions, however, are not negotiated at arm's length and thus, may result in unreasonable prices absent standards governing how those transactions should be priced; that is why the Commission adopted rules for the pricing of affiliate transactions decades ago. The Commission now invites parties to comment on whether there are circumstances surrounding transactions between non-affiliated parties that might raise concerns about whether the resulting prices are reasonable. For example, would a close family relationship or cross-participation on boards of directors be situations that warrant more scrutiny of the price? The Commission invites parties to discuss these examples and to identify other examples that might raise concerns. Parties are invited to discuss whether presumptions concerning what would be a prudent expenditure could be employed to ensure that prices are reasonable.

26. The Commission's rules require a carrier in specified situations to record the purchase of a good or service from an affiliate at fair market value. The Commission invites parties to comment on whether the affiliate transaction standard should also be applied to goods and services acquired from non-affiliated entities. If not, parties should propose an alternative standard and explain why it is a preferable approach. The Commission also invites parties to comment on the factors that should be considered in determining whether a transaction is a prudent expenditure or is a reasonable market price in evaluating prices in situations identified as warranting a closer look. Are there circumstances where a prudent expenditure might be something other than the absolute lowest identified price? Parties are invited to identify other metrics beside cost and reliability that are relevant in determining whether an investment or expense is prudent for the purposes of our rules. Finally, are there specific circumstances under which a carrier should be required to make a good faith determination of fair market value for a good or service obtained from a non-affiliate, prior to incurring such expenses, for instance

when the total aggregate annual value of the good(s) or service(s) reaches or exceeds a specified threshold for purchases from a non-affiliate, as is done under section 32.27(b)(3) and (c)(3) for affiliates?

27. Finally, the Commission invites parties to comment on the best manner of implementing any decision to exclude the expenses identified in this section. Specifically, parties should address whether it would be sufficient to adopt an order simply identifying and defining which costs are not allowed, as has generally been the process in the past, or whether some rule revisions are necessary. If rule revisions are thought necessary, parties should address where in the process they can best be implemented. Part 32 excludes certain investments and expenses as non-regulated, while Part 64 allocates investments and expenses used to provide both regulated and non-regulated activities that are recorded in the regulated accounts of Part 32 between regulated and non-regulated activities. In addition, for purposes of determining whether a carrier's realized rate-of-return exceeds the maximum allowable rate of return, Part 65 specifies the determination of earnings and rate base. Parties are encouraged to address whether some cost disallowances would be better achieved through revisions to the Part 32 rules, while other cost disallowances could best be addressed through revisions to other rules in Parts 64, 65, 69, or some combination of these rules. The Commission is providing state commissions with notice of this in compliance with the requirements of section 220(i) of the Act in the event they decide to make some revisions to Part 32. In other words, is it better to first enumerate which expenses should be excluded from the revenue requirement as not used and useful in the provision of regulated services and then proceed with allocating costs, or is it better to rely on the cost allocation procedures in Part 64 to exclude such expenses? One of the goals of the USOA at the time it was adopted was that it remain stable over time. How should this be factored into the decision of where to make certain disallowances? Parties are invited to submit proposed language to accomplish the approach they recommend. Lastly, the Commission invites parties to comment on whether they should require rate-of-return carriers to identify their cost consultants, if any, in their FCC Form 481s.

#### b. Issues Related to Cost Allocation and Affiliate Transactions

28. Rate-of-return carriers are subject to the Commission's longstanding Part 64 rules regarding the allocation of costs between regulated and non-regulated activities and to the affiliate transaction rules in Part 32. Under these rules, carriers currently apply broad principles in making such allocations, and the lack of specificity in the rules gives carriers a degree of discretion in making these allocation decisions. Therefore, there is an incentive to interpret the allocation rules in order to allocate as many costs as possible to their regulated activities, both to justify a higher interstate revenue requirement and to receive additional high-cost support. For instance, marketing costs could be recorded solely as regulated expenses, even though those marketing activities are designed to increase subscribership of retail broadband, *i.e.*, non-regulated services. Given the lack of specific guidance, the additional costs associated with the provision of retail broadband services, and the incentive to allocate costs to regulated activities, the Commission concludes that it is time to revisit our allocation rules in order to provide greater clarity to rate-of-return carriers regarding how to determine the relative allocation of costs between regulated and non-regulated activities and affiliates.

29. As noted, the Commission's existing cost allocation rules relating to regulated versus non-regulated activities generally provide that costs shall be directly assigned to either regulated or non-regulated activities where possible, and common costs are to be allocated according to a hierarchy of principles. To the extent costs cannot be allocated on direct or indirect cost causation principles, they are allocated based on a ratio of all expenses directly assigned or attributed to regulated and non-regulated activities. In certain cases, the affiliate transaction rule requires fully distributed costs to be used to determine the charge to the affiliate or the carrier.

30. The Commission seeks comment on adopting new rules to improve the process of allocating costs among regulated and non-regulated services and between affiliates. The Commission also seeks a better understanding of how to detect cases of misallocation. Our goal is to reduce the potential ability of carriers to include expenses associated with non-regulated services in their regulated revenue requirements, and to preclude carriers from artificially inflating their high-cost support through such actions. To this end, the Commission seeks comment on

adopting a rule that would classify certain costs, such as general and administrative expenses, as common costs for purposes of applying the Part 64 and affiliate transaction rules when an entity provides broadband services directly, or through an affiliated entity. Are there other costs that should be treated as common costs in applying these allocation rules? Under such an approach, carriers would be precluded from including all of these expenses in their regulated revenue requirement, and instead, would be required to exclude some expenses based on the prescribed manner of allocation. Accordingly, the Commission also seeks comment on adopting rules that would prescribe the manner of allocation of common costs in particular situations. For example, are there certain common costs that the Commission should specify by rule that they should be allocated on the basis of the relative number of regulated lines compared to the total number of lines (both regulated and non-regulated) for the rate-of-return carrier and its broadband affiliate, if any? Are there other instances in which relative revenues or some other measure would be a better allocator, taking into account the ease of administering any such rule?

31. The Commission is concerned about the potential for carriers to provide shared operational services to their affiliates under fully-distributed cost (FDC) allocation procedures that do not include all of the associated costs. The affiliate transaction rules employ a higher of cost or market standard when applicable, or a FDC standard to ensure that all costs of services provided by a regulated telecommunications company are recovered from its affiliates. The general nature of the FDC allocation guidelines, however, allows carriers significant discretion in performing the FDC cost study. This discretion allows carriers to exclude expenses associated with providing shared functions to their non-regulated affiliates, especially to those affiliates that then sell retail broadband services to end users on an unregulated basis, thus recovering these costs from rate payers. The Commission seeks comment on clarifying or adopting new rules to ensure the proper application of the affiliate transaction rules in light of provision of retail broadband by affiliates in certain telecommunications markets.

32. Our accounting and high-cost universal service support rules rely on proper allocation of costs to work as intended. The Commission seeks comment on specific instances in which additional rules or further clarification could minimize potential misallocations

and thereby protect ratepayers of regulated services. Are there other methods that would help ensure proper allocation of costs between regulated and non-regulated services?

33. The Commission is also concerned that problems similar to those associated with regulated versus non-regulated allocations may arise in the application of the FDC process in connection with affiliate transactions. Section 32.27 of the Commission's rules requires an incumbent LEC to record assets or services received from its affiliated entities at the lesser of FDC or fair market value when no tariff rate, prevailing price, or publicly filed agreement exists. FDC may be over-inclusive, however, if it includes investment and expenses of the affiliate that would not properly be included in a carrier's revenue requirement or calculations for high-cost support. While the used and useful and prudent expenditure standards apply to costs included in affiliate transactions, the Commission seeks comment on whether they should adopt a rule that explicitly prohibits carriers from including in the FDC of an affiliate any costs that are disallowed from the regulated rate base or revenue requirement, or considered not to be used and useful or prudent expenditures. Without such a rule, carriers could shift costs to an affiliate and then effectively recover those disallowed costs through payments to the affiliate. The Commission invites parties to comment on how such an approach could be implemented, and whether there are circumstances under which these costs of affiliates should be properly included in the regulated rate base or costs used to calculate high-cost support.

34. The Commission seeks comment on whether additional data would assist in enforcement of the Commission's accounting and cost allocation rules, while minimizing ETC reporting burden.

#### c. Compliance Issues

35. Finally, the Commission seeks comment on the most effective way to ensure compliance with the proposed rules for universal service support and tariffing purposes. Rate-of-return affiliates of price cap carriers would be subject to any revised rules in establishing their tariffed rates for interstate services. In addition, if a price cap carrier is required to make a cost-based showing in the future, any expense rules adopted in this proceeding would apply to such showings. The Commission invites parties to comment on whether they should require carriers to certify that

they have not included any prohibited expenses in their cost submissions used to calculate high-cost support. If so, is there a current certification that can be modified to encompass this aspect, or is a new rule necessary? Because audit findings can be used to recover overpayments of high-cost support, the Commission also invites parties to comment on how the Commission should implement any requirements it may adopt. Are there other proposals or considerations that the Commission should consider to ensure compliance with any revised requirements?

36. Ensuring compliance with any revised investment, expense, or cost allocation rules in the tariffing context raises different challenges. Rate-of-return carrier tariffs must be filed in advance of their effective date, and pursuant to section 204 of the Act, the Commission, during the notice period, may suspend the effectiveness of a tariff and initiate an investigation to determine whether the tariff is just and reasonable. Section 204(a)(3) provides that local exchange carrier tariffs that take effect on 7-days notice after filing (when rates are reduced) or 15-days notice (for any other change) after filing are "deemed lawful" unless rejected or suspended and investigated by the Commission. If a tariff investigation has not been completed within five months of the tariff's specified effective date, the proposed tariff goes into effect subject to the results of the investigation. At the conclusion of the investigation, the Commission may prescribe rates prospectively and order refunds as necessary for any period in which the tariff was in effect. With these constraints on timing and prohibition on retroactive relief, the Commission invites parties to comment on steps the Commission could take to ensure that carriers follow these requirements. As a starting point, the Commission proposes to require a certification and seek comment on what it should entail. The Commission also invites parties to comment on what sanctions should be used to give some meaning to the certifications.

37. The Commission invites parties to comment on whether, and if so, when an exception to the "deemed lawful" provision of section 204 of the Act would apply where a carrier violated these rules. The Commission notes that in *ACS v. FCC*, the D.C. Circuit indicated that although the "deemed lawful" language is unambiguous, "[w]e do not, of course, address the case of a carrier that furtively employs improper accounting techniques in a tariff filing, thereby concealing potential rate of return violations. The Order here makes

no claim of such misconduct.” The D.C. Circuit thus acknowledged that there may be extenuating circumstances (such as using improper accounting techniques or willfully misrepresenting expenses) that warrant an exception to the deemed lawful language. The Commission proposes to adopt a rule that would find an exception to the deemed lawful rule when a carrier incorrectly certifies that its revenue requirements are compliant with the applicable standards. The Commission invites parties to comment on this proposal. In particular, parties should address the amount of the discrepancy in actual and projected costs that must exist before such an exception would be invoked. The Commission also asks parties to comment on how any cost recovery should be returned to customers. For example, should it be used to reduce the revenue requirement for the following tariff period? Should there be an interest component to what must be returned to the customers. If so, what should the applicable interest rate be—the authorized rate of return, the corporate tax underpayment rate, or something else? Are there other mechanisms the Commission should consider to deter inclusion of inappropriate expenses in a rate-of-return carrier’s revenue requirement?

38. The vast majority of rate-of-return carriers are members of the NECA pool, and their costs are combined to establish pool rates. The Commission invites parties to comment on NECA’s role in enforcing these rules. Should carriers be barred from pool participation if determined to be including expenses prohibited by Commission rules? How should the magnitude of the violation be determined? What percent level of prohibited cost inclusion should be required before immediate expulsion from pool participation is deemed necessary? Are there any other metrics that should be considered in making this determination? Should carrier violations for inclusion of prohibited expenses have a “repeated occurrences” component, or should one time inclusion of a certain percentage of prohibited expenses impact pool participation?

#### *B. Reducing Support in Competitive Areas*

39. In section II.B of the concurrently adopted Report and Order, the Commission concludes that CAF BLS should not be provided in areas served by a qualifying unsubsidized competitor. The Commission adopts several methods of disaggregating Connect America Fund Broadband Loop

Support (CAF BLS) for areas found to be competitively service, and allow carriers to select which method will be used. USTelecom and NTCA propose that in addition to the methods they specifically presented, carriers should also have the option of disaggregating support based on a “method approved by the Commission.” Here, the Commission invites commenters to propose other methods of disaggregation of support that can be implemented with minimal administrative burden for affected carriers and USAC. The Commission seeks to avoid complex allocations of the cost of facilities that that serve both competitive and non-competitive areas, which could be burdensome for rate-of-return carriers to implement.

40. The Commission also invites parties to comment on how the non-supported amount is to be recovered by the carrier, assuming such expenses remain regulated expenses for ratemaking purposes. At the outset, the Commission notes that rate-of-return carriers currently receive compensation for interstate loop costs through a combination of end-user charges, *e.g.*, SLCs and universal service support. The SLCs most rate-of-return carriers assess are at the maximum levels. Thus, in many situations, carriers would be prohibited by our current rules from increasing SLC rates to recover investment and associated expenses that will not be supported under the high-cost program in competitive areas. The Commission invites parties to comment on the two approaches for recovery of those amounts.

41. First, the Commission could treat the non-supported expenses as being outside the tariffed regulated revenue requirement and allow carriers to assess a detariffed regulated rate to recover those non-supported costs. This would remove those costs from the NECA pooling process. The Commission invites parties to comment on whether the detariffed rates would be outside the prohibition on tariffing deaveraged rates in a study area, or whether a new rule should be adopted. The Commission invites parties to comment on this alternative. Does it present any opportunities for carriers to game the tariffing process?

42. A second option would be to raise the SLC caps for a particular study area to permit the recovery of the amounts not supported by the high-cost program. The Commission invites parties to comment on this alternative, including whether any SLC increases should be allowed only in the competitive area or should apply to the entire study area. In the former case, a modification of the

rule prohibiting deaveraging within the study area would need to be made. Parties should particularly address the effects of deaveraging on the NECA pooling and tariffing processes. The Commission also invites parties to comment on the effects of deaveraging on carriers’ billing and operation support systems. Are there other alternatives that the Commission should consider for recovery of the non-supported investment and associated expenses?

#### *C. Tribal Support*

43. *Discussion.* Given the difficulties that some carriers have experienced in deploying basic telecommunications services on Tribal lands, the Commission recognizes the important role of universal service support to foster the deployment of broadband in unserved areas. Therefore, the Commission seeks comment on adopting rules to increase support to rate-of-return carriers for census blocks that include Tribal lands and unserved with broadband meeting the Commission’s current requirements.

44. The Commission recognizes the distinct challenges in bringing communications services to Tribal lands and seek comment on how best to achieve broadband deployment on Tribal lands commensurate with that in other areas. However, the Commission has acknowledged that there are areas throughout the United States that are expensive to serve and that face challenges in demographics, weather, and geography.

45. NTTA proposes that a TBF be applied to any non-model-based rate-of-return mechanism that the Commission adopts. In light of the other changes adopted today, including measures to provide a larger capital investment allowance for carriers that are below average in terms of broadband deployment, and defined deployment obligations for all rate-of-return carriers, is there a need for a separate mechanism for Tribal lands? The Commission seeks comment on whether a multiplier applied to the revised ICLS (*i.e.* CAF BLS) mechanism would foster broadband deployment on Tribal lands and ensure “universal service funds are used for their intended purposes.” Are there other approaches that would better advance of our goals?

46. If the Commission determines that a multiplier of support amounts under CAF BLS is an appropriate mechanism, what factor is appropriate? NTTA provides little support of why 1.25x is the appropriate factor to ensure broadband deployment on Tribal lands, other than pointing to the 25 percent

credit the Commission provided in the Tribal Mobility Fund Phase I. The Commission seeks comment on the appropriate figure for the multiplier, if they were to adopt such an approach. When providing comment on the appropriate multiplier, specific data and figures are encouraged. The Commission also emphasizes that high-cost universal service support is a finite resource that must be equitably distributed in a manner that effectuates the goals of section 254. Therefore, the Commission seeks comment on how implementation of Tribal-specific additional support may affect the resources available to extend broadband deployment to non-Tribal rate-of-return service areas with equally minimal broadband build out and located in geographies as equally hard to serve as Tribal lands.

47. The Commission also seeks comment on how best to target Tribal land-specific support to Tribal lands most in need of broadband deployment. NTTA recommends offering TBF support to all rate-of-return carriers serving Tribal lands and limiting the applicability of the TBF to specific census blocks that include Tribal lands. As noted above, broadband deployment differs substantially among Tribal lands. In light of this, should all Tribal lands be eligible for additional support, or only those with lower levels of deployment? Above, the Commission adopts a mechanism to allow a larger allowable loop expenditure for carriers below the average and to limit the allowable loop expenditure for those above the average. The Commission notes that the weighted average nationwide for rate-of-return carrier deployment of 10/1 Mbps service is currently 68 percent. Should Tribal-specific support only be provided to those rate-of-return carriers that are serving Tribal lands that report broadband deployment lower than the weighted average, based on Form 477 data? If so, should eligibility for Tribal-specific support be determined annually or on a less frequent basis? Should it be provided for a specified period of time, and if so, what is the appropriate time period?

48. If a rate-of-return carrier's study area is mostly non-Tribal, should that carrier be eligible to receive additional Tribal-specific support? Should there be some threshold percentage, for example 50 percent, of a carrier's service area is on Tribal lands in order to qualify for additional Tribal-specific support? The Commission also seeks comment on the appropriate data source to use to determine whether a census block contains Tribal lands. For example, should the Commission utilize maps

and data distributed by the U.S. Census Bureau, or would maps and data provided by the Bureau of Indian Affairs be more appropriate? What other sources of data might the Commission use? The Commission notes that the Commission is currently engaged in consultation with the Tribal Nations of Oklahoma on the operational functionality and use of the Oklahoma Historical Map at the local and individual Tribal Nation level as part of the Lifeline rulemaking proceeding. The Commission seeks comment on how this process may affect our determination of which census blocks would be eligible for Tribal-specific support.

49. In addition, the Commission seeks comment on what specific broadband deployment obligations should be established, if they were to adopt a mechanism to provide additional support on Tribal lands that lag behind. NTTA supports tying build-out obligations to additional support, and proposes specific build-out obligations tied to a sliding scale based on current broadband deployment levels to "meaningfully improve broadband connectivity on Tribal lands . . . particularly in areas that are unserved today." For instance, it proposes that recipients of TBF that currently have deployed 10/1 Mbps to less than 10 percent of their locations be required to provide 4/1 Mbps service to at least 25 percent of their locations within three years, and 10/1 Mbps to at least 10 percent of locations, within three years; for those that already have deployed 10/1 Mbps to at least 10 percent but not 25 percent of their locations, they would be required to offer 4/1 Mbps service to 50 percent of their locations and 10/1 Mbps service to 25 percent of locations within three years. If the Commission were to adopt some form of additional Tribal-specific support, how should these proposals be harmonized with the mandatory deployment obligations they adopt above for all rate-of-return carriers?

50. NTTA recommends that participation in the TBF be voluntary. The Commission seeks comment on whether carriers should have the option to decline Tribal-specific support if the Commission determines that the provision of additional support to Tribal lands is necessary to close the broadband deployment gap in such areas. NTTA suggests that if acceptance of Tribal-specific support is conditioned on build-out obligations, such support presents a "unique opportunity to promote greater deployment of broadband to Tribal lands." Should

participation in such a program be mandatory?

51. In the *USF/ICC Transformation Order*, 76 FR 73830, November 29, 2011, the Commission required that ETCs serving Tribal lands must meaningfully engage with Tribal governments in their supported areas. The Commission seeks comment on whether the offer of additional voluntary Tribal-specific support would encourage more robust ETC engagement by carriers with Tribal governments on whose lands they provide service.

52. Finally, the Commission asks whether carriers that serve Tribal lands, in whole or in part, should not be subject to the measures to limit operating expenses and the overall budget control mechanism concurrently adopted in the Report and Order. Parties have noted, for instance, that Tribal lands may pose unique challenges for obtaining permitting and other authorizations. If the Commission were to exempt such providers from those opex and overall budget limitations, how should they determine the providers subject to such limitations? For instance, to be eligible for such an exemption, should 50 percent or more of the carrier's study area be Tribal lands? What would the budgetary impact be on other rate-of-return carriers that remain on legacy support mechanisms if the Commission were to adopt such exemptions?

#### *D. Other Measures To Improve the Operation of the Current Rate-of-Return System*

53. Some companies have informed us they have been unable to extend broadband despite their sincere desire to do so due to lack of access to capital. Some companies have seen declining support under the existing legacy mechanisms, and others are not eligible for high cost loop support (HCLS) support due to the prior "race to the top" that the Commission took steps to address in December 2014.

54. In the *April 2014 Connect America Fund FNPRM*, the Commission questioned the long term viability of HCLS and ICLS in their current form; that is why they encouraged stakeholders to focus on creating a Connect America Fund for cost recovery that would be consistent with our core principles for reform. As noted in the concurrently adopted Report and Order, the Commission expect the voluntary path to the model to be an attractive option for some of the carriers that no longer receive HCLS. Moreover, our reforms to the existing interstate common line support (ICLS) mechanism will enable carriers that are, relatively

speaking, lower cost than some of their peers to obtain more high-cost support for broadband only lines from CAF BLS than they would have received for voice-broadband lines under the existing HCLS mechanism. This may provide an incentive for them to migrate customers to broadband-only lines.

55. The Commission intends to monitor the impact of these reforms over time. The Commission are optimistic that together, these two paths will provide sufficient options for carriers to make a business case to extend broadband service where it is lacking, while minimizing disruption for those carriers that prefer to remain under the reformed legacy mechanisms. The Commission invites commenters to submit into the record any other proposals or ideas for steps the Commission should take to provide appropriate incentives for broadband deployment to unserved areas working within the framework of the existing budget for rate-of-return areas.

56. As the Commission evaluates ways to improve the overall framework governing rate-of-return carriers, they also believe it is appropriate to ensure that the administration of the current rate-of-return system, a function largely performed by NECA, is as efficient as possible to ensure that the costs of administration, ultimately borne by consumers, are reasonable. The role of NECA has changed over the last few decades due to a number of factors, including market changes, significant regulatory reforms, and the creation of USAC as the Administrator for the federal universal service mechanisms. The Commission asks parties to address whether and how the Commission should amend subpart G of Part 69 to reflect these changes. The Commission also seeks comment on whether they should adopt rule changes to facilitate transparency into and evaluation of whether NECA's functions are accomplished in an efficient, cost effective, and neutral manner.

#### *E. Streamlining ETC Annual Reporting Requirements*

57. In addition to the modifications to ETC annual reporting obligations adopted above, the Commission seeks comment on certain, narrowly-tailored reporting changes to improve the Commission's ability to protect against waste, fraud, and abuse. The Commission also seeks comment on additional ways to lessen regulatory reporting burdens on ETCs, particularly those that are small businesses.

58. Here, the Commission seeks comment on whether to modify or eliminate five sets of requirements:

specifically, the requirements by ETCs to provide outage information, unfulfilled service requests, the number of complaints per 1,000 subscribers for both voice and broadband service, pricing for both voice and broadband, and certification that it is complying with applicable service quality standards. What are the regulatory costs associated with requiring such information to be included in the annual Form 481, particularly for those categories of information that may be collected in some fashion through other means (the Commission's outage reporting system and consumer complaint system)? In the case of outage reporting, the Commission notes that all carriers are under a separate obligation to report outages under part 4 of our rules. Are the ETC-specific rules therefore duplicative, and can other means of collection be improved?

59. To the extent commenters believe such information should continue to be collected from ETCs, the Commission asks for specific suggestions on how to modify these requirements so that the information is more useful to analyze, both on an individual ETC and aggregate basis.

60. The underlying purpose of the unfulfilled service request reporting rule was to monitor rate-of-return carriers' progress in deploying broadband pursuant to the reasonable request standard. The Commission has concerns, however, that the rule, as implemented, is not adequately advancing that purpose. Similarly, the Commission has found the information regarding complaints to be of limited value, in large part because it is not clear that ETCs are reporting such information in a consistent fashion. If the Commission were to retain some form of reporting requirements for complaints and unfulfilled requests, should they implement more specific standardized instructions regarding the reporting of complaints and unfulfilled requests so that the information can be analyzed and aggregated in a more useful fashion? For the reporting of pricing information, would it be less burdensome if ETCs were to report only the price offering that meets or exceeds our minimum requirements, and not the full range of service offerings?

61. The Commission also seeks comment on whether, in light of our experience with the reporting requirements to date, they should modify or eliminate the requirement that an ETC certify it is complying with applicable service quality standards and consumer protection rules. Absent greater specificity, affected ETCs may not know what standards and rules are

“applicable.” Should the Commission clarify that the obligation applies only to legally binding rules and/or voluntary guidelines with which the ETC has agreed to comply? If so, how should the ETC report its compliance? Are other clarifications or modifications to the rule appropriate?

62. Above the Commission directs USAC to establish an online tool to permit access to all information submitted by ETCs, including Form 481 data. USAC shall ensure that state regulators, and Tribal governments where applicable, will have access full Form 481 data filings, including any data marked confidential. In light of that change, the Commission proposes to eliminate ETCs' requirement to file a duplicate copy of Form 481 with states and/or Tribal governments. Instead, they would make a single filing with USAC, and both the Commission and other regulators would obtain the information through online access. The Commission tentatively concludes that centralizing all filing requirements with USAC would be beneficial for states and Tribal governments as it would reduce the need to sort through, in some cases, dozens of paper documents containing the same information that would be available more readily through an online tool. Interested parties have suggested that the Commission should reduce or eliminate duplicate filings of the same information. Having one place for ETCs to file their annual reports, instead of three or more, may reduce the filing burden on ETCs. The Commission seeks comment on this tentative conclusion.

63. Lastly, the Commission seeks comment on modifying or eliminating any other reporting requirements applicable to all ETCs that have broadband obligations as a condition of receiving high-cost support in order to further improve the alignment of carriers' obligations with our ability to monitor them through our reporting requirements.

### **III. Procedural Matters**

#### *A. Paperwork Reduction Act Analysis*

64. This document contains new information collection requirements subject to the PRA. It will be submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the PRA. OMB, the general public, and other Federal agencies are invited to comment on the new information collection requirements contained in this proceeding. In addition, the Commission notes that pursuant to the Small Business Paperwork Relief Act of 2002, the Commission previously

sought specific comment on how the Commission might further reduce the information collection burden for small business concerns with fewer than 25 employees. The Commission describes impacts that might affect small businesses, which includes most businesses with fewer than 25 employees, in the Final Regulatory Flexibility Analysis (FRFA) in Appendix B, *infra*.

### B. Initial Regulatory Flexibility Analysis

65. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities from the policies and rules proposed in this Further Notice of Proposed Rulemaking. The Commission requests written public comment on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on the Further Notice provided on Further Notice of Proposed Rulemaking and the concurrently adopted Report and Order, Order and Order on Reconsideration. The Commission will send a copy of the Further Notice, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA). In addition, the Further Notice and IRFA (or summaries thereof) will be published in the **Federal Register**.

#### 1. Need for, and Objectives of, the Proposed Rules

66. In the Further Notice, the Commission commences a review of the extent to which certain investments and expenses incurred by a rate-of-return regulated local exchange carrier may be included in its rate base and revenue requirement for ratemaking and USF purposes. The Commission notes that there may be very limited circumstances where our proposed reforms would impact price cap regulated carriers' use of high-cost USF support. The Commission has not comprehensively reviewed the continued reasonableness of its existing rules regarding permissible investments and expenses for regulated local exchange carriers since the passage of the Telecommunications Act of 1996. Market and regulatory conditions have changed substantially since that time. Regulated telecommunications carriers have expanded into the provision of retail broadband services, either directly or through affiliated entities. Regulated carriers also increasingly face competition, for both voice and broadband services, in portions of their

incumbent territory from other facilities-based providers, such as cable and wireless providers. These changing conditions may affect the incentives regarding the types of costs carriers attempt to include in their revenue requirement and the ways in which carriers allocate costs between regulated and non-regulated services and affiliates.

67. Through audits, inquiries, and other investigations, the Commission has recently become aware of alleged abuses by rate-of-return carriers of the used and useful principles and its cost allocation rules. The Commission therefore concluded that it is time to reevaluate the types of expenses that should be permitted—both in a carrier's revenue requirement and for recovery through high-cost support. Looking into the expenses permitted and the allocation of those expenses will help ensure that carriers are only recovering costs that are used and useful and prudently incurred, and in the case of high cost support, only costs that are necessary to the provision of interstate telecommunications services.

68. In the concurrently adopted Order, the Commission determined that universal service support should be targeted more specifically to those areas where support is most needed to ensure consumers are served with voice and broadband service. Therefore, the Commission adopted a process for identifying those areas served by an unsubsidized competitor and several methods of disaggregating support to those areas. However, the Commission seeks comment on other methods for disaggregating support that would be minimally burdensome on carriers and how the non-supported amount should be recovered.

69. The Commission recognizes that Tribal lands may need additional financial support to ensure the availability of broadband in these areas. Therefore, the Further Notice seeks comment on whether a separate mechanism is needed to support broadband in Tribal lands and, if so, how such a mechanism should be structured.

70. Some companies have informed the Commission that they are unable to extend broadband due to a lack of access to capital. Other carriers have seen declining support or are ineligible for certain types of support, such as HCLS. In the concurrently adopted Order, the Commission has adopted reforms to its high-cost universal service support to support broadband deployment. The Further Notice seeks comment on other proposals to expand broadband services in those areas served

by rate-of-return carriers and any changes needed to make the administration of federal universal service programs more efficient.

71. The Commission also seeks to modify its ETC annual reporting obligations to improve the Commission's ability to protect against waste, fraud, and abuse. The Further Notice seeks comment on how best to make the information collected more useful while minimizing the burdens on those carriers subject to these reporting requirements.

#### 2. Review of Permitted Expenses

72. The Further Notice begins by reevaluating a rate-of-return carrier's ability to include certain types of expenses in its revenue requirement and high-cost support with consideration of the appropriate standard to be applied. The Commission believes that the terms "used and useful," "prudent expenditure," and "necessary to the provision of" should be read consistently to describe those expenses that a carrier may appropriately include in its interstate rate base, interstate revenue requirement, and cost studies used to calculate high-cost support. The costs should include amounts of long-term investment and current expenditures that a business would reasonably incur to provide telecommunications services, taking into account current and reasonably forecasted operating conditions and business levels. Accordingly, the Commission seeks comment on a variety of expenses, and whether such expenses should be included when making these calculations.

#### 3. Issues Related to Cost Allocation and Affiliate Transactions

73. Rate-of-return carriers are subject to the Commission's longstanding Part 64 rules regarding the allocation of costs between regulated and non-regulated activities and to the affiliate transaction rules in Part 32. Under these rules, carriers currently apply broad principles in making such allocations, and the lack of specificity in the rules gives carriers a degree of discretion in making these allocation decisions. Carriers have an incentive to interpret the allocation rules in order to allocate as many costs as possible to their regulated activities, both to justify a higher interstate revenue requirement and to receive additional high-cost support. Given the lack of specific guidance, the additional costs associated with the provision of retail broadband services, and the incentive to allocate costs to regulated activities, the Commission concludes that it is time to revisit the allocation

rules to provide greater clarity to rate-of-return carriers regarding how to determine the relative allocation of costs between regulated and non-regulated activities and affiliates. The Commission seeks comment on adopting new rules to improve the process of allocating costs among regulated and non-regulated services and among affiliates, and also seeks comment regarding how to detect cases of misallocation.

#### 4. Compliance Issues

74. Additionally, the Commission seeks comment on the most effective way to ensure compliance with the proposed rules for universal service support and tariffing purposes. For example, the Commission seeks comment on what, if any, certification or reporting requirements should be implemented.

#### 5. Reducing Support in Competitive Areas

75. In the Further Notice, the Commission seeks comment on alternative methods of reducing support for areas served by an unsubsidized competitor. In the concurrently adopted Order, the Commission adopts several methods of disaggregating CAF BLS for areas found to be competitively served and allow carriers to select which method will be used. However, the Commission invites commenters to propose other methods of disaggregation of support that can be implemented with minimal administrative burden for affected carriers and USAC. The Commission seeks to avoid complex allocations of the cost of facilities that serve both competitive and non-competitive areas, which could be burdensome for rate-of-return carriers to implement.

76. The Commission also invites parties to comment on how the non-supported amount is to be recovered by the carrier, assuming such expenses remain regulated expenses for ratemaking purposes. The Commission notes that rate-of-return carriers currently receive compensation for interstate loop costs through a combination of end-user charges, *e.g.*, SLCs, and universal service support. The SLCs most rate-of-return carriers assess are at the maximum levels. Thus, in many situations, carriers would be prohibited by our current rules from increasing SLC rates to recover investment and associated expenses that will not be supported under the high-cost program in competitive areas. Therefore, the Commission invites parties to comment on two approaches for recovery of those amounts.

#### 6. Tribal Support

77. In the Further Notice, the Commission seeks comment on a proposal to adopt a mechanism to provide additional support to unserved Tribal lands, and alternative approaches. The Commission has observed that communities on Tribal lands have historically had less access to telecommunications services than any other segment of the population, and that greater financial support therefore may be needed in order to ensure the availability of broadband on Tribal lands. Therefore, the Commission seeks comment on adopting rules to increase support to rate-of-return carriers for census blocks that include Tribal lands and are unserved with broadband meeting the Commission's current requirements. The Commission also recognizes that broadband deployment differs substantially among Tribal lands. To assist small rate-of-return carriers that serve Tribal areas with minimal infrastructure build out, the Commission also seeks comment on how best to target Tribal land-specific support to Tribal areas most in need of broadband deployment.

#### 7. Other Measures To Improve the Operation of the Current Rate-of-Return System

78. Additionally, in the Further Notice, the Commission invites commenters to submit into the record any other proposals or ideas for steps the Commission should take to provide appropriate incentives for broadband deployment to unserved areas working within the framework of the existing budget for rate-of-return areas. Some companies have indicated they have been unable to extend broadband despite their sincere desire to do so due to lack of access to capital, while other companies have seen declining support under the existing legacy mechanisms. Some carriers are not eligible for HCLS support due to the prior "race to the top" that the Commission took steps to address in December 2014. The Commission expects our reforms to the existing ICLS mechanism and addition of a voluntary path to the model will provide options for carriers to extend broadband where it is lacking. While the Commission intends to monitor the impact of these reforms over time, they invite commenters to submit into the record any other proposals or ideas for steps the Commission should take to provide appropriate incentives for broadband deployment to unserved areas while minimizing disruption for those carriers that prefer to remain under the reformed legacy mechanisms.

#### 8. Streamlining ETC Annual Reporting Requirements

79. Lastly, with respect to ETC reporting requirements, the Commission seeks comment on additional ways to lessen regulatory reporting burdens on ETCs, particularly those that are small businesses. In the concurrently adopted Order, the Commission updates our annual reporting requirements for rate-of-return ETCs as a necessary component of our ongoing efforts to update the support mechanisms for such ETCs to reflect our dual objectives of supporting existing voice and broadband service, while extending broadband to those areas of the country where it is lacking. To further lessen the regulatory burden on ETCs, many of whom are small rate-of-return carriers, and to improve on the Commission's ability to protect against waste, fraud, and abuse, the Commission seeks comment on certain, narrowly-tailored reporting changes. Specifically, the Commission seeks comment on whether to modify or eliminate five sets of requirements: the requirements to provide outage information, unfulfilled service requests, the number of complaints per 1,000 subscribers for both voice and broadband service, pricing for both voice and broadband, and certification of compliance with applicable service quality standards.

#### 9. Legal Basis

80. The legal basis for any action that may be taken pursuant to the Notice is contained in sections 1, 2, 4(i), 5, 10, 201-206, 214, 218-220, 251, 252, 254, 256, 303(r), 332, 403, and 405 of the Communications Act of 1934, as amended, and section 706 of the Telecommunications Act of 1996, 47 U.S.C. 151, 152, 154(i), 155, 201-206, 214, 218-220, 251, 252, 254, 256, 303(r), 332, 403, 405, 1302, and sections 1.1, 1.3, 1.421, 1.427, and 1.429 of the Commission's rules, 47 CFR 1.1, 1.3, 1.421, 1.427, and 1.429.

#### 10. Description and Estimate of the Number of Small Entities To Which the Rules Would Apply

81. 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 Small Business Administration (SBA).

#### 11. Total Small Entities

82. Our proposed action, if implemented, may, over time, affect small entities that are not easily categorized at present. The Commission therefore describes here, at the outset, three comprehensive, statutory small entity size standards. First, nationwide, there are a total of approximately 28.2 million small businesses, according to the SBA, which represents 99.7% of all businesses in the United States. 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.” Nationwide, as of 2007, there were approximately 1,621,215 small organizations. 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.” Census Bureau data for 2011 indicate that there were 90,056 local governmental jurisdictions in the United States. The Commission estimates that, of this total, as many as 89,327 entities may qualify as “small governmental jurisdictions.” Thus, the Commission estimates that most governmental jurisdictions are small.

#### 12. Broadband Internet Access Service Providers

83. The rules adopted in the concurrently adopted Order apply to broadband Internet access service providers. The Economic Census places these firms, whose services might include Voice over Internet Protocol (VoIP), in either of two categories, depending on whether the service is provided over the provider’s own telecommunications facilities (e.g., cable and DSL ISPs), or over client-supplied telecommunications connections (e.g., dial-up ISPs). The former are within the category of Wired Telecommunications Carriers, which has an SBA small business size standard of 1,500 or fewer employees. These are also labeled “broadband.” The latter are within the category of All Other Telecommunications, which has a size standard of annual receipts of \$32.5 million or less. These are labeled non-broadband. According to Census Bureau data for 2007, there were 3,188 firms in the first category, total, that operated for the entire year. Of this total, 3144 firms

had employment of 999 or fewer employees, and 44 firms had employment of 1,000 employees or more. For the second category, the data show that 2,383 firms operated for the entire year. Of those, 2,346 had annual receipts below \$32.5 million per year. Consequently, the Commission estimates that the majority of broadband Internet access service provider firms are small entities.

84. The broadband Internet access service provider industry has changed since this definition was introduced in 2007. The data cited above may therefore include entities that no longer provide broadband Internet access service, and may exclude entities that now provide such service. To ensure that this FRFA describes the universe of small entities that our action might affect, the Commission discusses in turn several different types of entities that might be providing broadband Internet access service. The Commission notes that, although they have no specific information on the number of small entities that provide broadband Internet access service over unlicensed spectrum, they include these entities in our Final Regulatory Flexibility Analysis.

#### 13. Wireline Providers

85. *Incumbent Local Exchange Carriers (Incumbent LECs)*. Neither the Commission nor the SBA has developed a small business size standard specifically for incumbent LEC services. The closest applicable 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, 1,307 carriers reported that they were incumbent LEC 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 LEC service are small businesses that may be affected by rules adopted pursuant to the concurrently adopted Order.

86. *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, seventy 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 rules adopted pursuant to the concurrently adopted Order.

87. The Commission has 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. The Commission has therefore included small incumbent LECs in this RFA analysis, although the Commission emphasizes that this RFA action has no effect on Commission analyses and determinations in other, non-RFA contexts.

88. *Interexchange Carriers*. Neither the Commission nor the SBA has developed a small business size standard specifically for providers of interexchange services. 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, 359 carriers have reported that they are engaged in the provision of interexchange service. Of these, 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 IXCs are small entities that may be affected by rules adopted pursuant to the concurrently adopted Order.

89. *Operator Service Providers (OSPs)*. Neither the Commission nor the SBA has developed a small business size

standard specifically for operator 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, 33 carriers have reported that they are engaged in the provision of operator services. Of these, an estimated 31 have 1,500 or fewer employees and two have more than 1,500 employees. Consequently, the Commission estimates that the majority of OSPs are small entities that may be affected by rules adopted pursuant to the concurrently adopted Order.

90. *Prepaid Calling Card Providers.* Neither the Commission nor the SBA has developed a small business size standard specifically for prepaid calling card providers. The appropriate size standard under SBA rules is for the category Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 193 carriers have reported that they are engaged in the provision of prepaid calling cards. Of these, an estimated all 193 have 1,500 or fewer employees and none have more than 1,500 employees. Consequently, the Commission estimates that the majority of prepaid calling card providers are small entities that may be affected by rules adopted pursuant to the concurrently adopted Order.

91. *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 rules adopted pursuant to the concurrently adopted Order.

92. *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 rules adopted pursuant to the concurrently adopted Order.

93. *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 the rules and policies adopted pursuant to the Order.

94. *800 and 800-Like Service Subscribers.* Neither the Commission nor the SBA has developed a small business size standard specifically for 800 and 800-like service (toll free) subscribers. The appropriate size standard under SBA rules is for the category Telecommunications Resellers. Under that size standard, such a business is small if it has 1,500 or fewer employees. The most reliable source of information regarding the number of these service subscribers appears to be data the Commission collects on the 800, 888, 877, and 866 numbers in use. According to our data, as of September 2009, the number of 800 numbers assigned was 7,860,000; the number of 888 numbers assigned was 5,588,687; the number of 877 numbers assigned was 4,721,866; and the number of 866 numbers assigned was 7,867,736. The Commission does not have data specifying the number of these subscribers that are not independently owned and operated or have more than 1,500 employees, and thus are unable at this time to estimate with greater precision the number of toll free subscribers that would qualify as small businesses under the SBA size standard. Consequently, the Commission estimates that there are 7,860,000 or fewer small entity 800 subscribers; 5,588,687 or fewer small entity 888 subscribers; 4,721,866 or fewer small entity 877 subscribers; and 7,867,736 or fewer small entity 866 subscribers.

14. *Wireless Providers—Fixed and Mobile*

95. The broadband Internet access service provider category covered by the concurrently adopted Order may cover multiple wireless firms and categories of regulated wireless services. Thus, to the extent the wireless services listed below are used by wireless firms for broadband Internet access service, the proposed actions may have an impact on those small businesses as set forth above and further below. In addition, for those services subject to auctions, the Commission notes that, as a general matter, the number of winning bidders that claim to qualify as small businesses at the close of an auction does not necessarily represent the number of small businesses currently in service. Also, the Commission does not generally track subsequent business size unless, in the context of assignments and transfers or reportable eligibility events, unjust enrichment issues are implicated.

96. *Wireless Telecommunications Carriers (except Satellite).* Since 2007, the Census Bureau has placed wireless firms within this new, broad, economic census category. Under the present and prior categories, the SBA has deemed a wireless business to be small if it has 1,500 or fewer employees. For the category of Wireless Telecommunications Carriers (except Satellite), census data for 2007 show that there were 1,383 firms that operated for the entire year. Of this total, 1,368 firms had employment of 999 or fewer employees and 15 had employment of 1,000 employees or more. Since all firms with fewer than 1,500 employees are considered small, given the total employment in the sector, the Commission estimates that the vast majority of wireless firms are small.

97. *Wireless Communications Services.* This service can be used for fixed, mobile, radiolocation, and digital audio broadcasting satellite uses. The Commission defined “small business” for the wireless communications services (WCS) auction as an entity with average gross revenues of \$40 million for each of the three preceding years, and a “very small business” as an entity with average gross revenues of \$15 million for each of the three preceding years. The SBA has approved these definitions.

98. *218–219 MHz Service.* The first auction of 218–219 MHz spectrum resulted in 170 entities winning licenses for 594 Metropolitan Statistical Area (MSA) licenses. Of the 594 licenses, 557 were won by entities qualifying as a small business. For that auction, the

small business size standard was an entity that, together with its affiliates, has no more than a \$6 million net worth and, after federal income taxes (excluding any carry over losses), has no more than \$2 million in annual profits each year for the previous two years. In the 218–219 MHz Report and Order and Memorandum Opinion and Order, 64 FR 59656, November 3, 1999, the Commission established a small business size standard for a “small business” as an entity that, together with its affiliates and persons or entities that hold interests in such an entity and their affiliates, has average annual gross revenues not to exceed \$15 million for the preceding three years. A “very small business” is defined as an entity that, together with its affiliates and persons or entities that hold interests in such an entity and its affiliates, has average annual gross revenues not to exceed \$3 million for the preceding three years. These size standards will be used in future auctions of 218–219 MHz spectrum.

99. *2.3 GHz Wireless Communications Services.* This service can be used for fixed, mobile, radiolocation, and digital audio broadcasting satellite uses. The Commission defined “small business” for the wireless communications services (“WCS”) auction as an entity with average gross revenues of \$40 million for each of the three preceding years, and a “very small business” as an entity with average gross revenues of \$15 million for each of the three preceding years. The SBA has approved these definitions. The Commission auctioned geographic area licenses in the WCS service. In the auction, which was conducted in 1997, there were seven bidders that won 31 licenses that qualified as very small business entities, and one bidder that won one license that qualified as a small business entity.

100. *1670–1675 MHz Services.* This service can be used for fixed and mobile uses, except aeronautical mobile. An auction for one license in the 1670–1675 MHz band was conducted in 2003. One license was awarded. The winning bidder was not a small entity.

101. *Wireless Telephony.* Wireless telephony includes cellular, personal communications services, and specialized mobile radio telephony carriers. As noted, the SBA has developed a small business size standard for Wireless Telecommunications Carriers (except Satellite). Under the SBA small business size standard, a business is small if it has 1,500 or fewer employees. According to Commission data, 413 carriers reported that they were engaged in wireless telephony. Of these, an

estimated 261 have 1,500 or fewer employees and 152 have more than 1,500 employees. Therefore, a little less than one third of these entities can be considered small.

102. *Broadband Personal Communications Service.* The broadband personal communications services (PCS) spectrum is divided into six frequency blocks designated A through F, and the Commission has held auctions for each block. The Commission initially defined a “small business” for C– and F–Block licenses as an entity that has average gross revenues of \$40 million or less in the three previous calendar years. For F–Block licenses, an additional small business size standard for “very small business” was added and is defined as an entity that, together with its affiliates, has average gross revenues of not more than \$15 million for the preceding three calendar years. These small business size standards, in the context of broadband PCS auctions, have been approved by the SBA. No small businesses within the SBA-approved small business size standards bid successfully for licenses in Blocks A and B. There were 90 winning bidders that claimed small business status in the first two C–Block auctions. A total of 93 bidders that claimed small business status won approximately 40 percent of the 1,479 licenses in the first auction for the D, E, and F Blocks. On April 15, 1999, the Commission completed the reauction of 347 C–, D–, E–, and F–Block licenses in Auction No. 22. Of the 57 winning bidders in that auction, 48 claimed small business status and won 277 licenses.

103. On January 26, 2001, the Commission completed the auction of 422 C and F Block Broadband PCS licenses in Auction No. 35. Of the 35 winning bidders in that auction, 29 claimed small business status. Subsequent events concerning Auction 35, including judicial and agency determinations, resulted in a total of 163 C and F Block licenses being available for grant. On February 15, 2005, the Commission completed an auction of 242 C–, D–, E–, and F–Block licenses in Auction No. 58. Of the 24 winning bidders in that auction, 16 claimed small business status and won 156 licenses. On May 21, 2007, the Commission completed an auction of 33 licenses in the A, C, and F Blocks in Auction No. 71. Of the 12 winning bidders in that auction, five claimed small business status and won 18 licenses. On August 20, 2008, the Commission completed the auction of 20 C–, D–, E–, and F–Block Broadband PCS licenses in Auction No. 78. Of the

eight winning bidders for Broadband PCS licenses in that auction, six claimed small business status and won 14 licenses.

104. *Specialized Mobile Radio Licenses.* The Commission awards “small entity” bidding credits in auctions for Specialized Mobile Radio (SMR) geographic area licenses in the 800 MHz and 900 MHz bands to firms that had revenues of no more than \$15 million in each of the three previous calendar years. The Commission awards “very small entity” bidding credits to firms that had revenues of no more than \$3 million in each of the three previous calendar years. The SBA has approved these small business size standards for the 900 MHz Service. The Commission has held auctions for geographic area licenses in the 800 MHz and 900 MHz bands. The 900 MHz SMR auction began on December 5, 1995, and closed on April 15, 1996. Sixty bidders claiming that they qualified as small businesses under the \$15 million size standard won 263 geographic area licenses in the 900 MHz SMR band. The 800 MHz SMR auction for the upper 200 channels began on October 28, 1997, and was completed on December 8, 1997. Ten bidders claiming that they qualified as small businesses under the \$15 million size standard won 38 geographic area licenses for the upper 200 channels in the 800 MHz SMR band. A second auction for the 800 MHz band was held on January 10, 2002 and closed on January 17, 2002 and included 23 BEA licenses. One bidder claiming small business status won five licenses.

105. The auction of the 1,053 800 MHz SMR geographic area licenses for the General Category channels began on August 16, 2000, and was completed on September 1, 2000. Eleven bidders won 108 geographic area licenses for the General Category channels in the 800 MHz SMR band and qualified as small businesses under the \$15 million size standard. In an auction completed on December 5, 2000, a total of 2,800 Economic Area licenses in the lower 80 channels of the 800 MHz SMR service were awarded. Of the 22 winning bidders, 19 claimed small business status and won 129 licenses. Thus, combining all four auctions, 41 winning bidders for geographic licenses in the 800 MHz SMR band claimed status as small businesses.

106. In addition, there are numerous incumbent site-by-site SMR licenses and licensees with extended implementation authorizations in the 800 and 900 MHz bands. The Commission does not know how many firms provide 800 MHz or 900 MHz geographic area SMR service pursuant to extended implementation

authorizations, nor how many of these providers have annual revenues of no more than \$15 million. One firm has over \$15 million in revenues. In addition, the Commission does not know how many of these firms have 1,500 or fewer employees, which is the SBA-determined size standard. The Commission assumes, for purposes of this analysis, that all of the remaining extended implementation authorizations are held by small entities, as defined by the SBA.

107. *Lower 700 MHz Band Licenses.* The Commission previously adopted criteria for defining three groups of small businesses for purposes of determining their eligibility for special provisions such as bidding credits. The Commission defined a “small business” as an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding \$40 million for the preceding three years. A “very small business” is defined as an entity that, together with its affiliates and controlling principals, has average gross revenues that are not more than \$15 million for the preceding three years. Additionally, the lower 700 MHz Service had a third category of small business status for Metropolitan/Rural Service Area (MSA/RSA) licenses—“entrepreneur”—which is defined as an entity that, together with its affiliates and controlling principals, has average gross revenues that are not more than \$3 million for the preceding three years. The SBA approved these small size standards. An auction of 740 licenses (one license in each of the 734 MSAs/RSAs and one license in each of the six Economic Area Groupings (EAGs)) commenced on August 27, 2002, and closed on September 18, 2002. Of the 740 licenses available for auction, 484 licenses were won by 102 winning bidders. Seventy-two of the winning bidders claimed small business, very small business or entrepreneur status and won a total of 329 licenses. A second auction commenced on May 28, 2003, closed on June 13, 2003, and included 256 licenses: 5 EAG licenses and 476 Cellular Market Area licenses. Seventeen winning bidders claimed small or very small business status and won 60 licenses, and nine winning bidders claimed entrepreneur status and won 154 licenses. On July 26, 2005, the Commission completed an auction of 5 licenses in the Lower 700 MHz band (Auction No. 60). There were three winning bidders for five licenses. All three winning bidders claimed small business status.

108. In 2007, the Commission reexamined its rules governing the 700

MHz band in the *700 MHz Second Report and Order*, 72 FR 48814, August 24, 2007. An auction of 700 MHz licenses commenced January 24, 2008 and closed on March 18, 2008, which included, 176 Economic Area licenses in the A Block, 734 Cellular Market Area licenses in the B Block, and 176 EA licenses in the E Block. Twenty winning bidders, claiming small business status (those with attributable average annual gross revenues that exceed \$15 million and do not exceed \$40 million for the preceding three years) won 49 licenses. Thirty three winning bidders claiming very small business status (those with attributable average annual gross revenues that do not exceed \$15 million for the preceding three years) won 325 licenses.

109. *Upper 700 MHz Band Licenses.* In the *700 MHz Second Report and Order*, the Commission revised its rules regarding Upper 700 MHz licenses. On January 24, 2008, the Commission commenced Auction 73 in which several licenses in the Upper 700 MHz band were available for licensing: 12 Regional Economic Area Grouping licenses in the C Block, and one nationwide license in the D Block. The auction concluded on March 18, 2008, with 3 winning bidders claiming very small business status (those with attributable average annual gross revenues that do not exceed \$15 million for the preceding three years) and winning five licenses.

110. *700 MHz Guard Band Licensees.* In 2000, in the *700 MHz Guard Band Order*, 65 FR 17594, April 4, 2000, the Commission adopted size standards for “small businesses” and “very small businesses” for purposes of determining their eligibility for special provisions such as bidding credits and installment payments. A small business in this service is an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding \$40 million for the preceding three years. Additionally, a very small business is an entity that, together with its affiliates and controlling principals, has average gross revenues that are not more than \$15 million for the preceding three years. SBA approval of these definitions is not required. An auction of 52 Major Economic Area licenses commenced on September 6, 2000, and closed on September 21, 2000. Of the 104 licenses auctioned, 96 licenses were sold to nine bidders. Five of these bidders were small businesses that won a total of 26 licenses. A second auction of 700 MHz Guard Band licenses commenced on February 13, 2001, and closed on February 21, 2001. All eight of the licenses auctioned were sold to

three bidders. One of these bidders was a small business that won a total of two licenses.

111. *Cellular Radiotelephone Service.* Auction 77 was held to resolve one group of mutually exclusive applications for Cellular Radiotelephone Service licenses for unserved areas in New Mexico. Bidding credits for designated entities were not available in Auction 77. In 2008, the Commission completed the closed auction of one unserved service area in the Cellular Radiotelephone Service, designated as Auction 77. Auction 77 concluded with one provisionally winning bid for the unserved area totaling \$25,002.

112. *Private Land Mobile Radio (“PLMR”).* PLMR systems serve an essential role in a range of industrial, business, land transportation, and public safety activities. These radios are used by companies of all sizes operating in all U.S. business categories, and are often used in support of the licensee’s primary (non-telecommunications) business operations. For the purpose of determining whether a licensee of a PLMR system is a small business as defined by the SBA, the Commission uses the broad census category, Wireless Telecommunications Carriers (except Satellite). This definition provides that a small entity is any such entity employing no more than 1,500 persons. The Commission does not require PLMR licensees to disclose information about number of employees, so the Commission does not have information that could be used to determine how many PLMR licensees constitute small entities under this definition. The Commission notes that PLMR licensees generally use the licensed facilities in support of other business activities, and therefore, it would also be helpful to assess PLMR licensees under the standards applied to the particular industry subsector to which the licensee belongs.

113. As of March 2010, there were 424,162 PLMR licensees operating 921,909 transmitters in the PLMR bands below 512 MHz. The Commission notes that any entity engaged in a commercial activity is eligible to hold a PLMR license, and that any revised rules in this context could therefore potentially impact small entities covering a great variety of industries.

114. *Rural Radiotelephone Service.* The Commission has not adopted a size standard for small businesses specific to the Rural Radiotelephone Service. A significant subset of the Rural Radiotelephone Service is the Basic Exchange Telephone Radio System (BETRS). In the present context, the Commission will use the SBA’s small

business size standard applicable to Wireless Telecommunications Carriers (except Satellite), *i.e.*, an entity employing no more than 1,500 persons. There are approximately 1,000 licensees in the Rural Radiotelephone Service, and the Commission estimates that there are 1,000 or fewer small entity licensees in the Rural Radiotelephone Service that may be affected by the rules and policies proposed herein.

115. *Air-Ground Radiotelephone Service.* The Commission has previously used the SBA's small business size standard applicable to Wireless Telecommunications Carriers (except Satellite), *i.e.*, an entity employing no more than 1,500 persons. There are approximately 100 licensees in the Air-Ground Radiotelephone Service, and under that definition, the Commission estimates that almost all of them qualify as small entities under the SBA definition. For purposes of assigning Air-Ground Radiotelephone Service licenses through competitive bidding, the Commission has defined "small business" as an entity that, together with controlling interests and affiliates, has average annual gross revenues for the preceding three years not exceeding \$40 million. A "very small business" is defined as an entity that, together with controlling interests and affiliates, has average annual gross revenues for the preceding three years not exceeding \$15 million. These definitions were approved by the SBA. In May 2006, the Commission completed an auction of nationwide commercial Air-Ground Radiotelephone Service licenses in the 800 MHz band (Auction No. 65). On June 2, 2006, the auction closed with two winning bidders winning two Air-Ground Radiotelephone Services licenses. Neither of the winning bidders claimed small business status.

116. *Aviation and Marine Radio Services.* Small businesses in the aviation and marine radio services use a very high frequency (VHF) marine or aircraft radio and, as appropriate, an emergency position-indicating radio beacon (and/or radar) or an emergency locator transmitter. The Commission has not developed a small business size standard specifically applicable to these small businesses. For purposes of this analysis, the Commission uses the SBA small business size standard for the category Wireless Telecommunications Carriers (except Satellite), which is 1,500 or fewer employees. Census data for 2007, which supersede data contained in the 2002 Census, show that there were 1,383 firms that operated that year. Of those 1,383, 1,368 had fewer than 100 employees, and 15 firms had more than 100 employees. Most

applicants for recreational licenses are individuals. Approximately 581,000 ship station licensees and 131,000 aircraft station licensees operate domestically and are not subject to the radio carriage requirements of any statute or treaty. For purposes of our evaluations in this analysis, the Commission estimates that there are up to approximately 712,000 licensees that are small businesses (or individuals) under the SBA standard. In addition, between December 3, 1998 and December 14, 1998, the Commission held an auction of 42 VHF Public Coast licenses in the 157.1875–157.4500 MHz (ship transmit) and 161.775–162.0125 MHz (coast transmit) bands. For purposes of the auction, the Commission defined a "small" business as an entity that, together with controlling interests and affiliates, has average gross revenues for the preceding three years not to exceed \$15 million dollars. In addition, a "very small" business is one that, together with controlling interests and affiliates, has average gross revenues for the preceding three years not to exceed \$3 million dollars. There are approximately 10,672 licensees in the Marine Coast Service, and the Commission estimates that almost all of them qualify as "small" businesses under the above special small business size standards and may be affected by rules adopted pursuant to the concurrently adopted Order.

117. *Advanced Wireless Services (AWS) (1710–1755 MHz and 2110–2155 MHz bands (AWS-1); 1915–1920 MHz, 1995–2000 MHz, 2020–2025 MHz and 2175–2180 MHz bands (AWS-2); 2155–2175 MHz band (AWS-3)).* For the AWS-1 bands, the Commission has defined a "small business" as an entity with average annual gross revenues for the preceding three years not exceeding \$40 million, and a "very small business" as an entity with average annual gross revenues for the preceding three years not exceeding \$15 million. For AWS-2 and AWS-3, although the Commission does not know for certain which entities are likely to apply for these frequencies, they note that the AWS-1 bands are comparable to those used for cellular service and personal communications service. The Commission has not yet adopted size standards for the AWS-2 or AWS-3 bands but proposes to treat both AWS-2 and AWS-3 similarly to broadband PCS service and AWS-1 service due to the comparable capital requirements and other factors, such as issues involved in relocating incumbents and developing markets, technologies, and services.

118. *3650–3700 MHz band.* In March 2005, the Commission released a *Report and Order and Memorandum Opinion and Order* that provides for nationwide, non-exclusive licensing of terrestrial operations, utilizing contention-based technologies, in the 3650 MHz band (*i.e.*, 3650–3700 MHz). As of April 2010, more than 1270 licenses have been granted and more than 7433 sites have been registered. The Commission has not developed a definition of small entities applicable to 3650–3700 MHz band nationwide, non-exclusive licensees. However, the Commission estimates that the majority of these licensees are Internet Access Service Providers (ISPs) and that most of those licensees are small businesses.

119. *Fixed Microwave Services.* Microwave services include common carrier, private-operational fixed, and broadcast auxiliary radio services. They also include the Local Multipoint Distribution Service (LMDS), the Digital Electronic Message Service (DEMS), and the 24 GHz Service, where licensees can choose between common carrier and non-common carrier status. At present, there are approximately 36,708 common carrier fixed licensees and 59,291 private operational-fixed licensees and broadcast auxiliary radio licensees in the microwave services. There are approximately 135 LMDS licensees, three DEMS licensees, and three 24 GHz licensees. The Commission has not yet defined a small business with respect to microwave services. For purposes of the FRFA, the Commission will use the SBA's definition applicable to Wireless Telecommunications Carriers (except satellite)—*i.e.*, an entity with no more than 1,500 persons. Under the present and prior categories, the SBA has deemed a wireless business to be small if it has 1,500 or fewer employees. The Commission does not have data specifying the number of these licensees that have more than 1,500 employees, and thus is unable at this time to estimate with greater precision the number of fixed microwave service licensees that would qualify as small business concerns under the SBA's small business size standard. Consequently, the Commission estimates that there are up to 36,708 common carrier fixed licensees and up to 59,291 private operational-fixed licensees and broadcast auxiliary radio licensees in the microwave services that may be small and may be affected by the rules and policies adopted herein. The Commission notes, however, that the common carrier microwave fixed licensee category includes some large entities.

120. *Offshore Radiotelephone Service.* This service operates on several UHF television broadcast channels that are not used for television broadcasting in the coastal areas of states bordering the Gulf of Mexico. There are presently approximately 55 licensees in this service. The Commission is unable to estimate at this time the number of licensees that would qualify as small under the SBA's small business size standard for the category of Wireless Telecommunications Carriers (except Satellite). Under that SBA small business size standard, a business is small if it has 1,500 or fewer employees. Census data for 2007, which supersede data contained in the 2002 Census, show that there were 1,383 firms that operated that year. Of those 1,383, 1,368 had fewer than 100 employees, and 15 firms had more than 100 employees. Thus, under this category and the associated small business size standard, the majority of firms can be considered small.

121. *39 GHz Service.* The Commission created a special small business size standard for 39 GHz licenses—an entity that has average gross revenues of \$40 million or less in the three previous calendar years. An additional size standard for “very small business” is: an entity that, together with affiliates, has average gross revenues of not more than \$15 million for the preceding three calendar years. The SBA has approved these small business size standards. The auction of the 2,173 39 GHz licenses began on April 12, 2000 and closed on May 8, 2000. The 18 bidders who claimed small business status won 849 licenses. Consequently, the Commission estimates that 18 or fewer 39 GHz licensees are small entities that may be affected by rules adopted pursuant to the concurrently adopted Order.

122. *Broadband Radio Service and Educational Broadband Service.* Broadband Radio Service systems, previously referred to as Multipoint Distribution Service (MDS) and Multichannel Multipoint Distribution Service (MMDS) systems, and “wireless cable,” transmit video programming to subscribers and provide two-way high speed data operations using the microwave frequencies of the Broadband Radio Service (BRS) and Educational Broadband Service (EBS) (previously referred to as the Instructional Television Fixed Service (ITFS)). In connection with the 1996 BRS auction, the Commission established a small business size standard as an entity that had annual average gross revenues of no more than \$40 million in the previous three calendar years. The BRS auctions

resulted in 67 successful bidders obtaining licensing opportunities for 493 Basic Trading Areas (BTAs). Of the 67 auction winners, 61 met the definition of a small business. BRS also includes licensees of stations authorized prior to the auction. At this time, the Commission estimates that of the 61 small business BRS auction winners, 48 remain small business licensees. In addition to the 48 small businesses that hold BTA authorizations, there are approximately 392 incumbent BRS licensees that are considered small entities. After adding the number of small business auction licensees to the number of incumbent licensees not already counted, the Commission finds that there are currently approximately 440 BRS licensees that are defined as small businesses under either the SBA or the Commission's rules.

123. In 2009, the Commission conducted Auction 86, the sale of 78 licenses in the BRS areas. The Commission offered three levels of bidding credits: (i) A bidder with attributed average annual gross revenues that exceed \$15 million and do not exceed \$40 million for the preceding three years (small business) received a 15 percent discount on its winning bid; (ii) a bidder with attributed average annual gross revenues that exceed \$3 million and do not exceed \$15 million for the preceding three years (very small business) received a 25 percent discount on its winning bid; and (iii) a bidder with attributed average annual gross revenues that do not exceed \$3 million for the preceding three years (entrepreneur) received a 35 percent discount on its winning bid. Auction 86 concluded in 2009 with the sale of 61 licenses. Of the ten winning bidders, two bidders that claimed small business status won 4 licenses; one bidder that claimed very small business status won three licenses; and two bidders that claimed entrepreneur status won six licenses.

124. In addition, the SBA's Cable Television Distribution Services small business size standard is applicable to EBS. There are presently 2,436 EBS licensees. All but 100 of these licenses are held by educational institutions. Educational institutions are included in this analysis as small entities. Thus, the Commission estimates that at least 2,336 licensees are small businesses. Since 2007, Cable Television Distribution 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.” The SBA has developed a small business size standard for this category, which is: all such firms having 1,500 or fewer employees. To gauge small business prevalence for these cable services the Commission must, however, use the most current census data that are based on the previous category of Cable and Other Program Distribution and its associated size standard; that size standard was: all such firms having \$13.5 million or less in annual receipts. According to Census Bureau data for 2007, there were a total of 996 firms in this category that operated for the entire year. Of this total, 948 firms had annual receipts of under \$10 million, and 48 firms had receipts of \$10 million or more but less than \$25 million. Thus, the majority of these firms can be considered small.

125. *Narrowband Personal Communications Services.* In 1994, the Commission conducted an auction for Narrowband PCS licenses. A second auction was also conducted later in 1994. For purposes of the first two Narrowband PCS auctions, “small businesses” were entities with average gross revenues for the prior three calendar years of \$40 million or less. Through these auctions, the Commission awarded a total of 41 licenses, 11 of which were obtained by four small businesses. To ensure meaningful participation by small business entities in future auctions, the Commission adopted a two-tiered small business size standard in the *Narrowband PCS Second Report and Order*, 65 FR 35843, June 6, 2000. A “small business” is an entity that, together with affiliates and controlling interests, has average gross revenues for the three preceding years of not more than \$40 million. A “very small business” is an entity that, together with affiliates and controlling interests, has average gross revenues for the three preceding years of not more than \$15 million. The SBA has approved these small business size standards. A third auction was conducted in 2001. Here, five bidders won 317 (Metropolitan Trading Areas and nationwide) licenses. Three of these claimed status as a small or very small entity and won 311 licenses.

126. *Paging (Private and Common Carrier).* In the *Paging Third Report and Order*, 64 FR 33762, June 24, 1999, the Commission developed a small business

size standard for “small businesses” and “very small businesses” for purposes of determining their eligibility for special provisions such as bidding credits and installment payments. A “small business” is an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding \$15 million for the preceding three years. Additionally, a “very small business” is an entity that, together with its affiliates and controlling principals, has average gross revenues that are not more than \$3 million for the preceding three years. The SBA has approved these small business size standards. According to Commission data, 291 carriers have reported that they are engaged in Paging or Messaging Service. Of these, an estimated 289 have 1,500 or fewer employees, and two have more than 1,500 employees. Consequently, the Commission estimates that the majority of paging providers are small entities that may be affected by our action. An auction of Metropolitan Economic Area licenses commenced on February 24, 2000, and closed on March 2, 2000. Of the 2,499 licenses auctioned, 985 were sold. Fifty-seven companies claiming small business status won 440 licenses. A subsequent auction of MEA and Economic Area (“EA”) licenses was held in the year 2001. Of the 15,514 licenses auctioned, 5,323 were sold. One hundred thirty-two companies claiming small business status purchased 3,724 licenses. A third auction, consisting of 8,874 licenses in each of 175 EAs and 1,328 licenses in all but three of the 51 MEAs, was held in 2003. Seventy-seven bidders claiming small or very small business status won 2,093 licenses. A fourth auction, consisting of 9,603 lower and upper paging band licenses was held in the year 2010. Twenty-nine bidders claiming small or very small business status won 3,016 licenses.

127. *220 MHz Radio Service—Phase I Licensees.* The 220 MHz service has both Phase I and Phase II licenses. Phase I licensing was conducted by lotteries in 1992 and 1993. There are approximately 1,515 such non-nationwide licensees and four nationwide licensees currently authorized to operate in the 220 MHz band. The Commission has not developed a small business size standard for small entities specifically applicable to such incumbent 220 MHz Phase I licensees. To estimate the number of such licensees that are small businesses, the Commission applies the small business size standard under the SBA rules applicable to Wireless Telecommunications Carriers (except Satellite). Under this category, the SBA

deems a wireless business to be small if it has 1,500 or fewer employees. The Commission estimates that nearly all such licensees are small businesses under the SBA’s small business size standard that may be affected by rules adopted pursuant to the concurrently adopted Order.

128. *220 MHz Radio Service—Phase II Licensees.* The 220 MHz service has both Phase I and Phase II licenses. The Phase II 220 MHz service is subject to spectrum auctions. In the *220 MHz Third Report and Order*, 62 FR 15978, April 3, 1997, the Commission adopted a small business size standard for “small” and “very small” businesses for purposes of determining their eligibility for special provisions such as bidding credits and installment payments. This small business size standard indicates that a “small business” is an entity that, together with its affiliates and controlling principals, has average gross revenues not exceeding \$15 million for the preceding three years. A “very small business” is an entity that, together with its affiliates and controlling principals, has average gross revenues that do not exceed \$3 million for the preceding three years. The SBA has approved these small business size standards. Auctions of Phase II licenses commenced on September 15, 1998, and closed on October 22, 1998. In the first auction, 908 licenses were auctioned in three different-sized geographic areas: three nationwide licenses, 30 Regional Economic Area Group (EAG) Licenses, and 875 Economic Area (EA) Licenses. Of the 908 licenses auctioned, 693 were sold. Thirty-nine small businesses won licenses in the first 220 MHz auction. The second auction included 225 licenses: 216 EA licenses and 9 EAG licenses. Fourteen companies claiming small business status won 158 licenses.

#### 15. Satellite Service Providers

129. *Satellite Telecommunications Providers.* Two economic census categories address the satellite industry. The first category has a small business size standard of \$30 million or less in average annual receipts, under SBA rules. The second has a size standard of \$30 million or less in annual receipts.

130. The category of Satellite Telecommunications “comprises establishments primarily engaged in providing telecommunications services to other establishments in the telecommunications and broadcasting industries by forwarding and receiving communications signals via a system of satellites or reselling satellite telecommunications.” For this category, Census Bureau data for 2007 show that there were a total of 570 firms that

operated for the entire year. Of this total, 530 firms had annual receipts of under \$30 million, and 40 firms had receipts of over \$30 million. Consequently, the Commission estimates that the majority of Satellite Telecommunications firms are small entities that might be affected by our action.

131. The second category of Other Telecommunications comprises, *inter alia*, “establishments primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems.” For this category, Census Bureau data for 2007 show that there were a total of 1,274 firms that operated for the entire year. Of this total, 1,252 had annual receipts below \$25 million per year. Consequently, the Commission estimates that the majority of All Other Telecommunications firms are small entities that might be affected by our action.

#### 16. Cable Service Providers

132. Because section 706 requires us to monitor the deployment of broadband using any technology, the Commission anticipates that some broadband service providers may not provide telephone service. Accordingly, the Commission describes below other types of firms that may provide broadband services, including cable companies, MDS providers, and utilities, among others.

133. *Cable and Other Program Distributors.* 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.” The SBA has developed a small business size standard for this category, which is: all such firms having 1,500 or fewer employees. To gauge small business prevalence for these cable services the Commission must, however, use current census data that are based on the previous category of Cable and Other Program Distribution

and its associated size standard; that size standard was: all such firms having \$13.5 million or less in annual receipts. According to Census Bureau data for 2007, there were a total of 2,048 firms in this category that operated for the entire year. Of this total, 1,393 firms had annual receipts of under \$10 million, and 655 firms had receipts of \$10 million or more. Thus, the majority of these firms can be considered small.

134. *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. Industry data that there are currently 4,600 active cable systems in the United States. Of this total, all but nine cable operators are small under the 400,000 subscriber size standard. In addition, under the Commission's rules, a "small system" is a cable system serving 15,000 or fewer subscribers. Current Commission records show 4,945 cable systems nationwide. Of this total, 4,380 cable systems have less than 20,000 subscribers, and 565 systems have 20,000 or more subscribers, based on the same records. Thus, under this standard, the Commission estimates that most cable systems are small entities.

135. *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." 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. Based on available data, the Commission finds that all but ten incumbent cable operators are small entities under this size standard. The Commission notes that the Commission neither requests nor collects information on whether cable system operators are affiliated with entities whose gross annual revenues exceed \$250 million, and therefore they are unable to estimate more accurately the number of cable system operators that would qualify as small under this size standard.

136. The open video system ("OVS") framework was established in 1996, and is one of four statutorily recognized

options for the provision of video programming services by local exchange carriers. The OVS framework provides opportunities for the distribution of video programming other than through cable systems. Because OVS operators provide subscription services, OVS falls within the SBA small business size standard covering cable services, which is "Wired Telecommunications Carriers." The SBA has developed a small business size standard for this category, which is: all such firms having 1,500 or fewer employees. According to Census Bureau data for 2007, there were a total of 955 firms in this previous category that operated for the entire year. Of this total, 939 firms had employment of 999 or fewer employees, and 16 firms had employment of 1,000 employees or more. Thus, under this second size standard, most cable systems are small and may be affected by rules adopted pursuant to the concurrently adopted Order. In addition, the Commission notes that they have certified some OVS operators, with some now providing service. Broadband service providers ("BSPs") are currently the only significant holders of OVS certifications or local OVS franchises. The Commission does not have financial or employment information regarding the entities authorized to provide OVS, some of which may not yet be operational. Thus, again, at least some of the OVS operators may qualify as small entities.

17. Electric Power Generators, Transmitters, and Distributors

137. *Electric Power Generators, Transmitters, and Distributors.* The Census Bureau defines an industry group comprised of "establishments, primarily engaged in generating, transmitting, and/or distributing electric power. Establishments in this industry group may perform one or more of the following activities: (1) Operate generation facilities that produce electric energy; (2) operate transmission systems that convey the electricity from the generation facility to the distribution system; and (3) operate distribution systems that convey electric power received from the generation facility or the transmission system to the final consumer." The SBA has developed a small business size standard for firms in this category: "A firm is small if, including its affiliates, it is primarily engaged in the generation, transmission, and/or distribution of electric energy for sale and its total electric output for the preceding fiscal year did not exceed 4 million megawatt hours." Census Bureau data for 2007 show that there were 1,174 firms that operated for the

entire year in this category. Of these firms, 50 had 1,000 employees or more, and 1,124 had fewer than 1,000 employees. Based on this data, a majority of these firms can be considered small.

18. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

138. *Permitted Expenses.* In the Further Notice, when reviewing permitted expenses, the Commission seeks comment on whether it should require rate-of-return carriers to identify their cost consultants, if any, in their FCC Form 481s.

139. *Cost Allocation and Affiliate Transactions.* The Commission seeks comment on adopting a rule that would classify certain costs, such as general and administrative expenses, as common costs for purposes of applying the Part 64 and affiliate transaction rules when an entity provides broadband services directly, or through an affiliated entity. Additionally, the Commission asks whether it should clarify or adopt new rules to ensure the proper application of the affiliate transaction rules in light of the provision of retail broadband by affiliates in certain telecommunications markets. More generally, the Commission seeks comment on instances in which additional rules or further clarification could minimize potential misallocations and thereby protect ratepayers of regulated services. While the Commission notes that the used and useful and prudent expenditure standards apply to costs included in affiliate transactions, it seeks comment on whether it should adopt a rule that explicitly prohibits carriers from including in the fully distributed cost of an affiliate any costs that are disallowed from the regulated rate base or revenue requirement, or considered not to be used and useful or prudent expenditures. Finally, the Commission seeks comment on whether additional data would assist in enforcement of the Commission's accounting and cost allocation rules, while minimizing ETC reporting burden, and if so, what kind of reporting requirements should be implemented.

140. *Compliance.* To ensure compliance with the proposed rules for universal service support and tariffing purposes, the Commission invites parties to comment on whether carriers should be required to certify that they have not included any prohibited expenses in their cost submissions used to calculate high-cost support. Additionally, the Commission asked parties to comment on NECA's role in



enforcing these rules, and whether carriers should be subject to any additional reporting requirements.

141. *Reducing Support in Competitive Areas.* In the Further Notice, the Commission also seeks comment on methods of disaggregation of support that can be implemented with minimal administrative burden for affected carriers and USAC. The Commission seeks to avoid complex allocations of the cost of facilities that serve both competitive and non-competitive areas, which could be burdensome for rate-of-return carriers to implement.

142. Additionally, the Commission asks how the non-supported amount is to be recovered by the carrier, assuming such expenses remain regulated expenses for ratemaking purposes. Specifically, the Commission invites parties to comment on two approaches for recovery of those amounts. First, the Commission could treat the non-supported expenses as being outside the tariffed regulated revenue requirement and allow carriers to assess a detariffed regulated rate to recover those non-supported costs. This would remove those costs from the NECA pooling process. The Commission invites parties to comment on whether the detariffed rates would be outside the prohibition on tariffing deaveraged rates in a study area, or whether a new rule should be adopted. A second option would be to raise the SLC caps for a particular study area to permit the recovery of the amounts not supported by the high-cost program. The Commission invites parties to comment on this alternative, including whether any SLC increases should be allowed only in the competitive area or should apply to the entire study area. Either of these alternatives would create new compliance requirements that could create administrative burdens for small rate-of-return carriers.

143. *Tribal Support.* The Commission seeks comment on adopting rules to increase support to rate-of-return carriers for census blocks that include Tribal lands and unserved with broadband meeting the Commission's current requirements. As part of this line of questioning, the Commission asks how to best to target Tribal land-specific support to Tribal areas most in need of broadband deployment, which may require filing on behalf of Tribal entities. Additionally, the Commission seeks comment on what specific broadband deployment obligations should be established, if the Commission were to adopt a mechanism to provide additional support on Tribal lands. Identification of specific areas to deploy and the associated deployment

obligations could place an administrative and resource burden on small rate-of-return carriers serving Tribal lands.

144. *Other Measures To Improve the Operation of the Current Rate-of-Return System.* The Commission invites commenters to submit into the record any other proposals or ideas for steps the Commission should take to provide appropriate incentives for broadband deployment to unserved areas working within the framework of the existing budget for rate-of-return areas. This line of questioning by the Commission is intended to gather new ideas or proposals for further consideration. Therefore, the Commission does not foresee any major burdens being placed on carriers as a result of this portion of the Further Notice.

145. *Streamlining ETC Annual Reporting Requirements.* Lastly, the Commission seeks comment on whether to modify or eliminate five sets of requirements for ETCS to provide: outage information, unfulfilled service requests, the number of complaints per 1,000 subscribers for both voice and broadband service, pricing for both voice and broadband, and certification that they are complying with applicable service quality standards. Elimination of these ETC reporting requirements would relieve the administrative burden on small rate-of-return carriers.

#### 19. Steps Taken To Minimize the Significant Economic Impact on Small Entities and Significant Alternatives Considered

146. The RFA requires an agency to describe any significant alternatives that it has considered in reaching its proposed approach, which may include (among others) the following four alternatives: (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. The Commission expects to consider all of these factors when they have received substantive comment from the public and potentially affected entities.

147. With respect to the costs of implementing the proposals to restrict permitted expenses, the Commission seeks comment on the least costly means of implementing any revisions, which would minimize burdens on carriers. The Commission notes that

many of the proposals with respect to cost allocation would most likely change the way cost allocation is completed, but would not necessarily be any more burdensome. The proposal of identifying cost consultants would add a minimal burden on small entities if adopted because carriers should typically utilize cost consultants to submit information to NECA for purposes of pooling.

148. In discussing potential compliance procedures, the Commission asks whether there is a current certification that can be modified to encompass a certification that only permitted expenses are included. This methodology seeks to reduce the burden on smaller entities by making a small change instead of creating a new, more involved compliance mechanism.

149. In the concurrently adopted Order, the Commission adopts several methods of disaggregating CAF BLS for areas found to be competitively served and allow carriers to select which method will be used. However, in seeking comment on other methods of disaggregation of support that can be implemented with minimal administrative burden for affected carriers and USAC, the Commission takes further steps to reduce administrative and resource burdens on small rate-of-return carriers. The Commission seeks to avoid complex allocations of the cost of facilities that serve both competitive and non-competitive areas, which could be burdensome for rate-of-return carriers to implement.

150. The Commission also invites parties to comment on how the non-supported amount is to be recovered by the carrier, assuming such expenses remain regulated expenses for ratemaking purposes. The Commission invites parties to comment on the two approaches for recovery of those amounts. The Commission seeks to minimize administrative burden under any approach.

151. The Commission also invites commenters to submit into the record any other proposals or ideas for steps the Commission should take to provide appropriate incentives for broadband deployment to unserved areas working within the framework of the existing budget for rate-of-return areas. The Commission is cognizant of the many compliance burdens small rate-of-return carriers face and seeks to minimize these burdens overall with this line of questioning.

152. In the concurrently adopted Order, the Commission updates our annual reporting requirements for rate-

of-return ETCs as a necessary component of our ongoing efforts to update the support mechanisms for such ETCs to reflect our dual objectives of supporting existing voice and broadband service, while extending broadband to those areas of the country where it is lacking. To further lessen the regulatory burden on small rate-of-return carriers, and to improve on the Commission's ability to protect against waste, fraud, and abuse they Commission seeks comment on certain, narrowly-tailored reporting changes. Specifically, the sets of requirements the Commission seeks comment on whether to modify or eliminate would reduce rate-of-returns ETCs' compliance burden.

153. More generally, the Commission expects to consider the economic impact on small entities, as identified in comments filed in response to the Notice and this IRFA, in reaching its final conclusions and taking action in this proceeding. The proposals and questions laid out in the Further Notice were designed to ensure the Commission has a complete understanding of the benefits and potential burdens associated with the different actions and methods.

#### 20. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

154. None.

#### C. Congressional Review Act

155. The Commission will send a copy of the concurrently adopted Report and Order to Congress and the Government Accountability Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A).

#### D. Ex Parte Presentations

156. *Permit-But-Disclose*. The proceeding this Second FNPRM initiates shall be treated as a "permit-but-disclose" proceeding in accordance with the Commission's *ex parte* rules. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation

consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda, or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule 1.1206(b). In proceedings governed by rule 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (e.g., .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

#### E. Comment Filing Procedures

157. *Comments and Replies*. 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://apps.fcc.gov/ecfs>.
- **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.

158. *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](mailto:fcc504@fcc.gov) or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (tty).

159. Comments and reply comments must include a short and concise summary of the substantive arguments raised in the pleading. Comments and reply comments must also comply with section 1.49 and all other applicable sections of the Commission's rules. The Commission directs all interested parties to include the name of the filing party and the date of the filing on each page of their comments and reply comments. All parties are encouraged to utilize a table of contents, regardless of the length of their submission. The Commission also strongly encourages parties to track the organization set forth in the FNPRM in order to facilitate our internal review process.

160. *Additional Information*. For additional information on this proceeding, contact Suzanne Yelen of the Wireline Competition Bureau, Industry Analysis and Technology Division, [Suzanne.Yelen@fcc.gov](mailto:Suzanne.Yelen@fcc.gov), (202) 418-7400 or Alexander Minard of the Wireline Competition Bureau, Technology Access Policy Division, [Alexander.Minard@fcc.gov](mailto:Alexander.Minard@fcc.gov), (202) 418-7400.

#### IV. Ordering Clauses

161. Accordingly, IT IS ORDERED, pursuant to the authority contained in sections 1, 2, 4(i), 5, 10, 201-206, 214, 218-220, 251, 252, 254, 256, 303(r), 332, 403, and 405 of the Communications Act of 1934, as amended, and section 706 of the Telecommunications Act of 1996, 47 U.S.C. 151, 152, 154(i), 155, 201-206, 214, 218-220, 251, 252, 254, 256, 303(r), 332, 403, 405, 1302, and sections 1.1, 1.3, 1.421, 1.427, and 1.429 of the Commission's rules, 47 CFR 1.1, 1.3, 1.421, 1.427, and 1.429, that this Further Notice of Proposed Rulemaking

and the concurrently adopted Report and Order, Order and Order on Reconsideration IS ADOPTED. It is our intention in adopting these rules that if any of the rules that the Commission retains, modifies, or adopts herein, or the application thereof to any person or circumstance, are held to be unlawful, the remaining portions of the rules not deemed unlawful, and the application of such rules to other persons or circumstances, shall remain in effect to the fullest extent permitted by law.

162. IT IS FURTHER ORDERED that, pursuant to the authority contained in sections 1, 2, 4(i), 5, 10, 201–206, 214, 218–220, 251, 252, 254, 256, 303(r), 332, 403, and 405 of the Communications Act of 1934, as amended, and section 706 of the Telecommunications Act of 1996, 47 U.S.C. 151, 152, 154(i), 155, 201–206, 214, 218–220, 251, 252, 254, 256, 303(r), 332, 403, 405, 1302, and sections 1.1, 1.3, 1.421, 1.427, and 1.429 of the Commission's rules, 47 CFR 1.1, 1.3, 1.421, 1.427, and 1.429, NOTICE IS HEREBY GIVEN of the proposals and tentative conclusions described in this Further Notice of Proposed Rulemaking.

163. IT IS FURTHER ORDERED that the Commission SHALL SEND a copy of this Further Notice of Proposed Rulemaking and the concurrently adopted Report and Order, Order and Order on Reconsideration to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

164. IT IS FURTHER ORDERED, that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, SHALL SEND a copy of this Further Notice of Proposed Rulemaking and the concurrently adopted Report and Order, Order and Order on Reconsideration, including the Initial Regulatory Flexibility Analysis and the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

#### List of Subjects in 47 CFR Part 65

Administrative practice and procedure, Communications common carriers, Reporting and recordkeeping requirements, Telephone.

Federal Communications Commission.

**Marlene H. Dortch,**  
*Secretary.*

#### Proposed Rules

For the reasons discussed in the preamble, the Federal Communications

Commission proposes to amend 47 CFR part 65 as follows:

### PART 65—INTERSTATE RATE OF RETURN PRESCRIPTION PROCEDURES AND METHODOLOGIES

- 1. The authority citation for part 65 is revised to read as follows:

**Authority:** 47 U.S.C. 151, 154, 201, 202, 203, 204, 205, 218, 219, 220, 403.

- 2. Amend § 65.450 by revising paragraph (d) and adding paragraph (e) to read as follows:

#### § 65.450 Net income.

\* \* \* \* \*

(d) Except for the allowance for funds used during construction and interest related to customer deposits, the amounts recorded as nonoperating income and expenses and taxes (Account 7300 and 7400) and interest and related items (Account 7500) and extraordinary items (Account 7600) shall not be included unless this Commission specifically determines that particular items recorded in those accounts shall be included.

(e) For purposes of determining whether an expense is recognized by the Commission as “necessary to the provision of these services” under paragraph (a) of this section, the expense must be used and useful and a prudent expenditure. The Commission specifically provides that the following expenses are not necessary to the provision of interstate telecommunications services regulated by the Commission:

(1) Personal travel; gifts to employees; childcare; housing allowances or other forms of mortgage or rent assistance for employees; personal expenses of employees, board members, family members of employees and board members, contractors, or any other individuals affiliated with the incumbent LEC, including but not limited to personal expenses for housing, such as rent or mortgages; personal use of company-owned housing, buildings, or facilities used for entertainment purposes by employees, board members, family members of employees and board members, contractors, or any other individuals affiliated with the incumbent local exchange carrier;

(2) Entertainment; artwork and other objects which possess aesthetic value; tangible property not logically related or

necessary to the offering of voice or broadband services;

(3) Aircraft, watercraft, and other motor vehicles designed for off-road use, except insofar as necessary to access inhabited portions of the study area not reachable by motor vehicles travelling on roads; any vehicles provided to employees, board members, family members of employees and board members, contractors, or any other individuals affiliated with the incumbent local exchange carrier for personal use;

(4) Cafeterias and dining facilities; alcohol and food, including but not limited to meals to celebrate personal events, such as weddings, births, or retirements, except that a reasonable amount for food shall be allowed for work-related travel;

(5) Political contributions; charitable donations; scholarships; membership fees and dues in clubs and organizations; sponsorships of conferences or community events; and

(6) Penalties or fines for statutory or regulatory violations; penalties or fees for any late payments on debt, loans, or other payments.

- 3. Add paragraph (d) to § 65.830 to read as follows:

#### § 65.830 Deducted items.

\* \* \* \* \*

(d) The following assets shall also be deducted from the interstate rate base:

(1) Artwork and other objects which possess aesthetic value;

(2) Tangible property not logically related or necessary to the offering of voice or broadband services;

(3) Personal residences and property used for entertainment purposes;

(4) Aircraft, watercraft, and other motor vehicles designed for off-road use, except insofar as necessary to access inhabited portions of the study area not reachable by motor vehicles travelling on roads;

(5) Any vehicles provided to employees, board members, family members of employees and board members, contractors, or any other individuals affiliated with the incumbent local exchange carrier for personal use; and

(6) Cafeterias and dining facilities.

[FR Doc. 2016–08376 Filed 4–11–16; 8:45 am]

BILLING CODE 6712–01–P

# Notices

Federal Register

Vol. 81, No. 70

Tuesday, April 12, 2016

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

### Rural Utility Service

#### Submission for OMB Review; Comment Request

April 6, 2016.

The Department of Agriculture has submitted the following information collection requirement(s) to Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104-13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by May 12, 2016 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th Street NW., Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: [OIRA\\_Submission@OMB.EOP.GOV](mailto:OIRA_Submission@OMB.EOP.GOV) or fax (202) 395-5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250-7602. Copies of the submission(s) may be obtained by calling (202) 720-8958.

An agency may not conduct or sponsor a collection of information

unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

### Rural Utilities Service

*Title:* 7 CFR 1778, Emergency and Imminent Community Water Assistance Grants.

*OMB Control Number:* 0572-0110.

*Summary of Collection:* The Rural Utilities Service (RUS) is authorized under Section 306A of the Consolidated Farm and Rural Development Act, (7 U.S.C. 1926(a)) to provide grants to rural areas and small communities to secure adequate quantities of safe water. There are two levels of grant limits—\$500,000 and \$150,000. Grants made under this program shall be made for 100 percent of the project's cost, can serve rural areas with population not in excess of 5,000, and household income should not exceed 100 percent of a State's non-metropolitan median household income. Grants under this program may be made to public bodies and private nonprofit corporations serving rural areas.

*Need and Use of the Information:* RUS will collect the information from applicants applying for grants under 7 CFR 1778. The information is unique to each borrower and emergency situation. Applicants must demonstrate that there is an imminent emergency or that a decline occurred within 2 years of the date the application was filed with Rural Development.

*Description of Respondents:* State, Local or Tribal Government; Not-for-profit institutions.

*Number of Respondents:* 100.

*Frequency of Responses:* Reporting: On occasion.

*Total Burden Hours:* 400.

#### Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2016-08339 Filed 4-11-16; 8:45 am]

**BILLING CODE 3410-15-P**

## CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

### Sunshine Act Meeting

**TIME AND DATE:** April 20, 2016, 1:00 p.m. EDT

**PLACE:** U.S. Chemical Safety Board, 1750 Pennsylvania Ave. NW., Suite 910, Washington, DC 20006.

**STATUS:** Open to the public.

**MATTERS TO BE CONSIDERED:** The Chemical Safety and Hazard Investigation Board (CSB) will convene a public meeting on April 20, 2016, starting at 1:00 p.m. EDT in Washington, DC, at the CSB offices located at 1750 Pennsylvania Avenue NW., Suite 910. The Board will discuss the status of open investigations; an update on audits from the Office of the Inspector General; financial and organizational updates; a review of the agency's action plan; and a calendared notation item related to recommendations 2001-01-H-R9 and 2001-01-H-R10 from the 2002 study on Improving Reactive Hazard Management. An opportunity for public comment will be provided.

### Additional Information

The meeting is free and open to the public. If you require a translator or interpreter, please notify the individual listed below as the "Contact Person for Further Information," at least three business days prior to the meeting.

A conference call line will be provided for those who cannot attend in person. Please use the following dial-in number to join the conference: 1-(888) 466-9863, passcode 6069134#.

The CSB is an independent federal agency charged with investigating accidents and hazards that result, or may result, in the catastrophic release of extremely hazardous substances. The agency's Board Members are appointed by the President and confirmed by the Senate. CSB investigations look into all aspects of chemical accidents and hazards, including physical causes such as equipment failure as well as inadequacies in regulations, industry standards, and safety management systems.

### Public Comment

The time provided for public statements will depend upon the number of people who wish to speak. Speakers should assume that their

presentations will be limited to three minutes or less, but commenters may submit written statements for the record.

#### Contact Person for Further Information

Hillary Cohen, Communication Manager, at [public@csb.gov](mailto:public@csb.gov) or (202) 446-8094. Further information about this public meeting can be found on the CSB Web site at: [www.csb.gov](http://www.csb.gov).

Dated: April 8, 2016.

#### Kara A. Wenzel,

Acting General Counsel, Chemical Safety and Hazard Investigation Board.

[FR Doc. 2016-08526 Filed 4-8-16; 4:15 pm]

BILLING CODE 6350-01-P

## COMMISSION ON CIVIL RIGHTS

### Sunshine Act Meeting Notice

**AGENCY:** United States Commission on Civil Rights.

**ACTION:** Notice of Commission business meeting.

**DATES:** Friday, April 15, 2016, at 10:00 a.m. EST.

**ADDRESSES:** *Place:* National Place Building, 1331 Pennsylvania Ave. NW., 11th Floor, Suite 1150, Washington, DC 20245 (Entrance on F Street NW.).

**FOR FURTHER INFORMATION CONTACT:** Gerson Gomez, Media Advisor at telephone: (202) 376-8371, TTY: (202) 376-8116 or email: [publicaffairs@usccr.gov](mailto:publicaffairs@usccr.gov).

**SUPPLEMENTARY INFORMATION:** This business meeting is open to the public. If you would like to listen to the business meeting, please contact the above for the call-in information. *Hearing-impaired persons who will attend the briefing and require the services of a sign language interpreter should contact Pamela Dunston at (202) 376-8105 or at [signlanguage@usccr.gov](mailto:signlanguage@usccr.gov) at least seven business days before the scheduled date of the meeting.*

#### Meeting Agenda

##### I. Approval of Agenda

##### II. Business Meeting

##### A. Program Planning

- Discussion on Commissioner Concept Papers and Statutory Enforcement Report for 2017
- Discussion and vote on Commission statement concerning North Carolina law on LGBT rights
- Discussion and vote on Commission statement concerning disparate impact that the Countering Violent Extremism (CVE) program will have on the Muslim community in the U.S.

- Discussion and vote on Commission statement concerning Parallel Construction (NSA data-sharing)

##### B. Advisory Committees

- Presentation by Nebraska State Advisory Committee Chair on report about impact of state law denying state services to individuals who cannot present documentation of legal status.

##### C. Management and Operations

- Staff Director's Report

##### III. State Advisory Committee (SAC) Appointments

- Georgia
- Maine

##### IV. Adjourn Meeting

Dated: April 8, 2016.

#### David Mussatt,

Regional Programs Unit Chief, U.S. Commission on Civil Rights.

[FR Doc. 2016-08477 Filed 4-8-16; 4:15 pm]

BILLING CODE 6335-01-P

## DEPARTMENT OF COMMERCE

### Bureau of Industry and Security

#### Information Systems, Technical Advisory Committee; Notice of Partially Closed Meeting

The Information Systems Technical Advisory Committee (ISTAC) will meet on April 27 and 28, 2016, 9:00 a.m., in the Herbert C. Hoover Building, Room 3884, 14th Street between Constitution and Pennsylvania Avenues NW., Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration on technical questions that affect the level of export controls applicable to information systems equipment and technology.

#### Wednesday, April 27

##### Open Session

1. Welcome and Introductions
2. Working Group Reports
3. Old Business
4. Industry Presentations
5. New Business

#### Thursday, April 28

##### Closed Session

6. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 sections 10(a)(1) and 10(a)(3).

The open session will be accessible via teleconference to 20 participants on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at [Yvette.Springer@bis.doc.gov](mailto:Yvette.Springer@bis.doc.gov), no later than April 20, 2016.

A limited number of seats will be available for the public session.

Reservations are not accepted. To the extent time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the Committee suggests that public presentation materials or comments be forwarded before the meeting to Ms. Springer.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on January 7, 2016, pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. app. 2 section 10(d)), that the portion of the meeting concerning trade secrets and commercial or financial information deemed privileged or confidential as described in 5 U.S.C. 552b(c)(4) and the portion of the meeting concerning matters the disclosure of which would be likely to frustrate significantly implementation of an agency action as described in 5 U.S.C. 552b(c)(9)(B) shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 sections 10(a)(1) and 10(a)(3). The remaining portions of the meeting will be open to the public.

For more information, call Yvette Springer at (202) 482-2813.

#### Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2016-08373 Filed 4-11-16; 8:45 am]

BILLING CODE 3510-JT-P

## DEPARTMENT OF COMMERCE

### Bureau of Industry and Security

#### Materials Technical Advisory Committee; Notice of Partially Closed Meeting

The Materials Technical Advisory Committee will meet on May 5, 2016, 10:00 a.m., Herbert C. Hoover Building, Room 3884, 14th Street between Constitution & Pennsylvania Avenues NW., Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration with respect to technical questions that affect the level of export controls applicable to materials and related technology.

#### Agenda

##### Open Session

1. Opening remarks and Introductions.

2. Remarks from the Bureau of Industry and Security senior management.

3. Report by regime representatives.

4. Report by working groups (Composite Working Group, Biological Working Group, Pump and Valves Working Group, and the Chemicals Working Group).

5. Public Comments and New Business.

#### *Closed Session*

6. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3).

The open session will be accessible via teleconference to 20 participants on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at [Yvette.Springer@bis.doc.gov](mailto:Yvette.Springer@bis.doc.gov), no later than April 28, 2016.

A limited number of seats will be available during the public session of the meeting. Reservations are not accepted. To the extent time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the materials should be forwarded prior to the meeting to Ms. Springer via email.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on November 5, 2015, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. app. 2 § 10(d)), that the portion of the meeting dealing with pre-decisional changes to the Commerce Control List and the U.S. export control policies shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3). The remaining portions of the meeting will be open to the public.

For more information, call Yvette Springer at (202) 482-2813.

Dated: April 6, 2016.

**Yvette Springer,**

*Committee Liaison Officer.*

[FR Doc. 2016-08371 Filed 4-11-16; 8:45 am]

**BILLING CODE 3510-JT-P**

## **DEPARTMENT OF COMMERCE**

### **Bureau of Industry and Security**

#### **Sensors and Instrumentation Technical Advisory Committee; Notice of Partially Closed Meeting**

The Sensors and Instrumentation Technical Advisory Committee (SITAC) will meet on April 26, 2016, 9:30 a.m., in the Herbert C. Hoover Building, Room 3884, 14th Street between Constitution and Pennsylvania Avenues NW., Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration on technical questions that affect the level of export controls applicable to sensors and instrumentation equipment and technology.

#### **Agenda**

##### *Public Session*

1. Welcome and Introductions.
2. Remarks from the Bureau of Industry and Security Management.
3. Industry Presentations.
4. New Business.

##### *Closed Session*

5. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3).

The open session will be accessible via teleconference to 20 participants on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at [Yvette.Springer@bis.doc.gov](mailto:Yvette.Springer@bis.doc.gov) no later than April 19, 2016.

A limited number of seats will be available during the public session of the meeting. Reservations are not accepted. To the extent that time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate distribution of public presentation materials to the Committee members, the Committee suggests that the materials be forwarded before the meeting to Ms. Springer.

The Assistant Secretary for Administration, with the concurrence of the General Counsel, formally determined on November 5, 2015 pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. app. 2 § 10(d)), that the portion of this meeting dealing with pre-decisional changes to the Commerce Control List and U.S. export control policies shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 §§ 10(a)(1) and 10(a)(3). The remaining

portions of the meeting will be open to the public.

For more information contact Yvette Springer on (202) 482-2813.

Dated: April 6, 2016.

**Yvette Springer,**

*Committee Liaison Officer.*

[FR Doc. 2016-08372 Filed 4-11-16; 8:45 am]

**BILLING CODE P**

## **DEPARTMENT OF COMMERCE**

### **Bureau of Industry and Security**

#### **Transportation and Related Equipment Technical Advisory Committee; Notice of Partially Closed Meeting**

The Transportation and Related Equipment Technical Advisory Committee will meet on May 4, 2016, 9:30 a.m., in the Herbert C. Hoover Building, Room 3884, 14th Street between Constitution & Pennsylvania Avenues NW., Washington, DC. The Committee advises the Office of the Assistant Secretary for Export Administration with respect to technical questions that affect the level of export controls applicable to transportation and related equipment or technology.

#### **Agenda**

##### *Public Session*

1. Welcome and Introductions.
2. Status reports by working group chairs.
3. Public comments and Proposals.

##### *Closed Session*

4. Discussion of matters determined to be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 sections 10(a)(1) and 10(a)(3).

The open session will be accessible via teleconference to 20 participants on a first come, first serve basis. To join the conference, submit inquiries to Ms. Yvette Springer at [Yvette.Springer@bis.doc.gov](mailto:Yvette.Springer@bis.doc.gov) no later than April 27, 2016.

A limited number of seats will be available during the public session of the meeting. Reservations are not accepted. To the extent time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the Committee suggests that presenters forward the public presentation materials prior to the meeting to Ms. Springer via email.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on November 5,

2015, pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. app. 2 section 10(d)), that the portion of the meeting dealing with pre-decisional changes to the Commerce Control List and U.S. export control policies shall be exempt from the provisions relating to public meetings found in 5 U.S.C. app. 2 sections 10(a)(1) and 10(a)(3). The remaining portions of the meeting will be open to the public.

For more information, call Yvette Springer at (202) 482-2813.

Dated: April 6, 2016.

**Yvette Springer,**

*Committee Liaison Officer.*

[FR Doc. 2016-08379 Filed 4-11-16; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

[A-549-821]

#### **Polyethylene Retail Carrier Bags From Thailand: Preliminary Results of Antidumping Duty Administrative Review; 2014-2015**

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on polyethylene retail carrier bags (PRCBs) from Thailand. The period of review (POR) is August 1, 2014, through July 31, 2015. We preliminarily find that subject merchandise has been sold at less than normal value by K. International Packaging Co., Ltd. (K. International Packaging).<sup>1</sup>

**DATES:** *Effective Date:* April 12, 2016.

**FOR FURTHER INFORMATION CONTACT:** Andre Gziryan, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401

<sup>1</sup> We initiated a review of 45 companies and subsequently rescinded the review with respect to 44 companies pursuant to a timely withdrawal of the request for review. See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 80 FR 60356 (October 6, 2015); see also *Polyethylene Retail Carrier Bags From Thailand: Rescission of Antidumping Duty Administrative Review in Part; 2014-2015*, 80 FR 45952 (August 3, 2015); see also, See the Memorandum from Andre Gziryan to James Maeder titled "Polyethylene Retail Carrier Bags from Thailand: Selection of Respondents for Individual Examination" at footnote 5 for clarification on the company name (K. International Packaging Co., Ltd. is also known as "K. International Packing Co., Ltd.").

Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482-2201.

#### **SUPPLEMENTARY INFORMATION:**

##### **Scope of the Order**

The merchandise subject to this order is polyethylene retail carrier bags, which are currently classified under subheading 3923.21.0085 of the Harmonized Tariff Schedule of the United States (HTSUS). While the HTSUS subheadings are provided for convenience and customs purposes, the written description is dispositive. A full description of the scope of the order is contained in the Preliminary Decision Memorandum.<sup>2</sup>

##### **Tolling of Deadline of Preliminary Results of Review**

As explained in the memorandum from the Acting Assistant Secretary for Enforcement and Compliance, the Department has exercised its discretion to toll all administrative deadlines due to the recent closure of the Federal Government. All deadlines in this segment of the proceeding have been extended by four business days. The revised deadline for the preliminary results of this review is now May 6, 2016.<sup>3</sup>

##### **Methodology**

We have relied on total facts available with respect to K. International Packaging, the sole company subject to this review. Because this company did not act to the best of its ability to respond to the Department's requests for information, we have drawn an adverse inference in selecting from among the facts otherwise available.<sup>4</sup> We have preliminarily determined to apply a 122.88 percent rate as adverse facts available for K. International Packaging.<sup>5</sup>

##### **Preliminary Results of Review**

As a result of our review, we preliminarily determine that a weighted-average dumping margin of

<sup>2</sup> See the Memorandum from Deputy Assistant Secretary Christian Marsh to Acting Assistant Secretary Ronald K. Lorentzen entitled, "Preliminary Decision Memorandum for the Administrative Review of the Antidumping Duty Order on Polyethylene Retail Carrier Bags from Thailand" dated concurrently with and hereby adopted by this notice (Preliminary Decision Memorandum).

<sup>3</sup> See Memorandum to the Record from Ron Lorentzen, Acting A/S for Enforcement & Compliance, regarding "Tolling of Administrative Deadlines As a Result of the Government Closure During Snowstorm Jonas" dated January 27, 2016.

<sup>4</sup> See sections 776(a) and (b) of the Tariff Act of 1930, as amended (the Act).

<sup>5</sup> For a full description of the methodology underlying our conclusions, see Preliminary Decision Memorandum.

122.88 percent exists for K. International Packaging Co., Ltd. on PRCBs from Thailand for the period August 1, 2014, through July 31, 2015.

##### **Public Comment**

Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs not later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.<sup>6</sup> Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue, (2) a brief summary of the argument, and (3) a table of authorities.<sup>7</sup>

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically *via* ACCESS. An electronically filed document must be received successfully in its entirety by the Department's electronic records system, ACCESS, by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice.<sup>8</sup> Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. The Department will issue the final results of this administrative and new shipper 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 shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review. For the final results, if we continue to rely on total adverse facts available to establish K. International Packaging's weighted-average dumping margin, we will instruct CBP to apply an *ad valorem* assessment rate of 122.88 percent to all entries of subject merchandise during the POR which were produced and/or exported by K. International Packaging.

We intend to issue liquidation instructions to CBP 15 days after

<sup>6</sup> See 19 CFR 351.309(d).

<sup>7</sup> See 19 CFR 351.309(c)(2) and (d)(2).

<sup>8</sup> See 19 CFR 351.310(c).

publication of the final results of review.

### Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of PRCBs from Thailand entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(2) of the Act: (1) The cash deposit rate for the reviewed company will be the rate established in the final results of this review; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair-value investigation but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; (4) if neither the exporter nor the manufacturer has its own rate, the cash deposit rate will be 4.69 percent.<sup>9</sup> These deposit requirements, when imposed, shall remain in effect until further notice.

### Notifications to Importer

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) 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 doubled antidumping duties.

These preliminary results of administrative review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: April 6, 2016.

**Ronald K. Lorentzen,**

Acting Assistant Secretary for Enforcement and Compliance.

### Appendix

#### List of Topics Discussed in the Preliminary Decision Memorandum

- Summary
- Background
- Scope of the Order
- Discussion of the Methodology
  - A. Use of Facts Available
  - B. Application of Facts Available With an Adverse Inference
  - C. Selection and Corroboration of Information Used as Facts Available

<sup>9</sup> See Section 129 Determination.

Recommendation

[FR Doc. 2016-08385 Filed 4-11-16; 8:45 am]

BILLING CODE 3510-DS-P

## DEPARTMENT OF COMMERCE

### International Trade Administration

[C-570-938]

#### Citric Acid and Certain Citrate Salts From the People's Republic of China: Notice of Court Decision Not in Harmony With Final Results of Countervailing Duty Administrative Review and Notice of Amended Final Results Pursuant to Court Decision; 2011

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** On March 30, 2016, the United States Court of International Trade (CIT) sustained the Department of Commerce's (Department's) final results of redetermination,<sup>1</sup> which recalculated the subsidy rate for RZBC Group Shareholding Co., Ltd., RZBC Co., Ltd., RZBC Imp. & Exp. Co., Ltd., and RZBC (Juxian) Co., Ltd. (collectively, RZBC Companies) in the administrative review of the countervailing duty (CVD) order on citric acid and certain citrate salts (citric acid) from the People's Republic of China for the period January 1, 2011, through December 31, 2011,<sup>2</sup> pursuant to the CIT's remand order in *RZBC Companies v. United States*.<sup>3</sup> Consistent with the decision of the United States Court of Appeals for the Federal Circuit (CAFC) in *Timken*,<sup>4</sup> as clarified by *Diamond Sawblades*,<sup>5</sup> the Department is notifying the public that the Court's final judgment in this case is not in harmony with the *Final Results* and that the Department is amending the *Final Results* with respect to the RZBC Companies.

**DATES:** *Effective Date:* April 9, 2016.

<sup>1</sup> See *RZBC Group Shareholding Co., Ltd., RZBC Co., Ltd., RZBC Imp. & Exp. Co., Ltd., and RZBC (Juxian) Co., Ltd. v. United States*, Court No. 14-00041 (CIT March 30, 2016) (Court Order affirming remand redetermination) (*RZBC Companies v. United States II*).

<sup>2</sup> See *Citric Acid and Certain Citrate Salts From the People's Republic of China: Final Results of Countervailing Duty Administrative Review*; 2011, 79 FR 108 (January 2, 2014) (*Final Results*) and accompanying Issues and Decision Memorandum (Final IDM).

<sup>3</sup> See *RZBC Group Shareholding Co., Ltd., RZBC Co., Ltd., RZBC Imp. & Exp. Co., Ltd., and RZBC (Juxian) Co., Ltd. v. United States*, Court No. 14-00041, Slip Op. 15-83 (August 5, 2015) (*RZBC Companies v. United States*).

<sup>4</sup> See *Timken Co. v. United States*, 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

<sup>5</sup> See *Diamond Sawblades Mfrs. Coalition v. United States*, 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

### FOR FURTHER INFORMATION CONTACT:

Patricia M. Tran, AD/CVD Operations, Office III, Enforcement and Compliance, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482-1503.

### SUPPLEMENTARY INFORMATION:

#### Background

In the *Final Results*, the Department elected to simple-average all available benchmark data for steam coal, sulfuric acid, and calcium carbonate because they were not reported in a uniform manner.<sup>6</sup> The CIT remanded for the Department to reevaluate the world benchmarks for steam coal, sulfuric acid, and calcium carbonate subsidies. Specifically, the CIT instructed the Department to consider whether to calculate world-average prices using weighted or simple-averages in light of small-quantity, high-price transactions in the underlying data, and to comply with the mandate to measure the adequacy of remuneration in light of prevailing market conditions in the country subject to review.<sup>7</sup> The CIT also directed the Department to recalculate the respondents' countervailing duty rate consistent with any reevaluated benchmark prices for steam coal, sulfuric acid, and calcium carbonate.<sup>8</sup>

In its final results of redetermination pursuant to *RZBC Companies v. United States*, the Department reopened and placed on the record in the remand proceeding world benchmark information for steam coal, sulfuric acid, and calcium carbonate. The Department then calculated weighted-average monthly world benchmarks for sulfuric acid and calcium carbonate. For steam coal, we weight-averaged the weightable data<sup>9</sup> on the record while continuing to utilize the data from other unweightable<sup>10</sup> sources.

On March 30, 2016, the CIT sustained the Department's final results of redetermination pursuant to remand.<sup>11</sup>

#### Timken Notice

In its decision in *Timken*, as clarified by *Diamond Sawblades*, the CAFC held that, pursuant to section 516A(e) of the Tariff Act of 1930, as amended (the Act), the Department must publish a notice of a court decision that is not "in

<sup>6</sup> See *Final Results* and Final IDM at Comment 13E.

<sup>7</sup> See *RZBC Companies v. United States*, Slip Op. at 40.

<sup>8</sup> *Id.*

<sup>9</sup> Weightable data contains benchmark prices and quantity.

<sup>10</sup> Unweightable data contains only benchmark prices.

<sup>11</sup> See *RZBC Companies v. United States II*.



harmony” with a Department determination and must suspend liquidation of entries pending a “conclusive” court decision. The CIT’s opinion in *RZBC Companies v. United States II*, issued on March 30, 2016, sustaining the Department’s final results of redetermination constitutes a final decision of the court that is not in harmony with the Department’s *Final Results*. This notice is published in fulfillment of the publication requirements of *Timken*. Accordingly, the Department will continue the suspension of liquidation of the subject merchandise pending the expiration of the period of appeal or, if appealed, pending a final and conclusive court decision.

#### Amended Final Results of Review

Because there is now a final court decision with respect to the *Final Results*, the Department amends its *Final Results*. The Department finds that the following revised net countervailable subsidy rate is:

Company	Net countervailable subsidy rate
RZBC Group Shareholding Co., Ltd., RZBC Co., Ltd., RZBC Imp. & Exp. Co., Ltd., and RZBC (Juxian) Co., Ltd. (collectively, RZBC Companies).	18.28 percent <i>ad valorem</i> .

Since the *Final Results*, the Department established a new cash deposit rate for RZBC Companies.<sup>12</sup> Therefore, the cash deposit rate for RZBC Companies does not need to be updated as a result of these amended final results. In the event that the CIT’s ruling is not appealed, or if appealed, upheld by the CAFC, the Department will instruct U.S. Customs and Border Protection to liquidate entries of subject merchandise that were exported by RZBC Companies, and which were entered, or withdrawn from warehouse, for consumption during the period January 1, 2011, through December 31, 2011, at the revised rate of 18.28 percent *ad valorem*.

This notice is issued and published in accordance with sections 516A(e)(1), 751(a)(1), and 777(i)(1) of the Act.

Dated: April 5, 2016.

**Ronald K. Lorentzen,**

*Acting Assistant Secretary for Enforcement and Compliance.*

[FR Doc. 2016–08387 Filed 4–11–16; 8:45 am]

**BILLING CODE 3510–DS–P**

<sup>12</sup> See *Citric Acid and Certain Citrate Salts: Final Results of Countervailing Duty Administrative Review; 2013*, 80 FR 77318 (December 14, 2015).

## DEPARTMENT OF COMMERCE

### International Trade Administration

[Application No. 84–26A12]

#### Export Trade Certificate of Review

**ACTION:** Notice of issuance of an amended Export Trade Certificate of Review to the Northwest Fruit Exporters of Washington (“NFE”), Application No. (84–26A12).

**SUMMARY:** The Secretary of Commerce, through the Office of Trade and Economic Analysis (“OTEA”), issued an amended Export Trade Certificate of Review to NFE of California on March 21, 2016.

#### FOR FURTHER INFORMATION CONTACT:

Joseph E. Flynn, Director, Office of Trade and Economic Analysis, International Trade Administration, by telephone at (202) 482–5131 (this is not a toll-free number) or email at [etca@trade.gov](mailto:etca@trade.gov).

**SUPPLEMENTARY INFORMATION:** Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. An Export Trade Certificate of Review protects the holder and the members identified in the Certificate from State and Federal government antitrust actions and from private treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. The regulations implementing title III are found at 15 CFR part 325 (2016).

OTEA is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Secretary of Commerce to publish a summary of the certification in the **Federal Register**. Under section 305(a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary’s determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

#### Description of Amended Certificate

*NFE’s Export Trade Certificate of Review has been amended to:*

#### Description of Amendments to the Certificate

- Under the heading Products, add “fresh pears.”
- Under the heading Export Trade Activities and Methods of Operation, add “fresh pears” to the subtitles of sections 1 and 3.

- Add coverage for Export Trade Activities and Methods of Operation relating to “fresh pears” for the following existing Members of the Certificate (within the meaning of section 325.2(l) of the regulations (15 CFR 325.2(l))):

Apple House Warehouse & Storage, Inc.  
Blue Bird, Inc.  
Blue Star Growers, Inc.  
Borton & Sons, Inc.  
Chelan Fruit Cooperative  
Congdon Packing Co. L.L.C.  
Conrad & Adams Fruit L.L.C.  
Crane & Crane, Inc.  
Diamond Fruit Growers Inc.  
Gold Digger Apples, Inc.  
Hansen Fruit & Cold Storage Co., Inc.  
Highland Fruit Growers, Inc.  
HoneyBear Growers, LLC  
Matson Fruit Company  
McDougall & Sons, Inc.  
Stadelman Fruit, L.L.C.  
Stemilt Growers, LLC  
Strand Apples, Inc.  
The Dalles Fruit Company, LLC  
Valley Fruit III L.L.C.

- Add the following new Members of the Certificate (within the meaning of section 325.2(l) of the regulations (15 CFR 325.2(l))), for Export Trade Activities and Methods of Operation relating to “fresh pears”:  
Duckwall Fruit  
Naumes, Inc.  
Peshastin Hi-Up Growers  
Underwood Fruit & Warehouse Co.
  - Add the following new Members of the Certificate for Export Trade Activities and Methods of Operation relating to apples:  
Piepel Premium Fruit Packing LLC  
Ron LeFore, d/b/a Ron LeFore Apple Farms  
Western Traders LLC
  - Remove the following companies as Members of the Certificate: Blue Mountain Growers, Inc. (Milton-Freewater, OR), and Obert Cold Storage (Zillah, WA); and
  - Change the name of the following existing Members: The Apple House, Inc. (Brewster, WA) is now Apple House Warehouse & Storage, Inc. (Brewster, WA); C&M Fruit Packers (Yakima, WA) is now Columbia Fruit Packers/Airport Division (Yakima, WA); Domex Marketing (Yakima, WA) is now Domex Superfresh Growers LLC (Yakima, WA); and Stemilt Growers Inc. is now Stemilt Growers, LLC.  
*NFE’s complete Membership covered by the amended Export Trade Certificate of Review is listed below:*
- Allan Bros., Naches, WA

2. AltaFresh L.L.C. dba Chelan Fresh Marketing, Chelan, WA
3. Apple House Warehouse & Storage, Inc., Brewster, WA
4. Apple King, L.L.C., Yakima, WA
5. Auvil Fruit Co., Inc., Orondo, WA
6. Baker Produce, Inc., Kennewick, WA
7. Blue Bird, Inc., Peshastin, WA
8. Blue Star Growers, Inc., Cashmere, WA
9. Borton & Sons, Inc., Yakima, WA
10. Brewster Heights Packing & Orchards, LP, Brewster, WA
11. Broetje Orchards LLC, Prescott, WA
12. C.M. Holtzinger Fruit Co., Inc., Yakima, WA
13. Chelan Fruit Cooperative, Chelan, WA
14. Chiawana, Inc. dba Columbia Reach Pack, Yakima, WA
15. Columbia Fruit Packers, Inc., Wenatchee, WA
16. Columbia Fruit Packers/Airport Division, Yakima, WA
17. Columbia Marketing International Corp., Wenatchee, WA
18. Columbia Valley Fruit, L.L.C., Yakima, WA
19. Congdon Packing Co. L.L.C., Yakima, WA
20. Conrad & Adams Fruit L.L.C., Grandview, WA
21. Cowiche Growers, Inc., Cowiche, WA
22. CPC International Apple Company, Tieton, WA
23. Crane & Crane, Inc., Brewster, WA
24. Custom Apple Packers, Inc., Brewster, Quincy, and Wenatchee, WA
25. Diamond Fruit Growers, Odell, OR
26. Domex Superfresh Growers LLC, Yakima, WA
27. Douglas Fruit Company, Inc., Pasco, WA
28. Dovex Export Company, Wenatchee, WA
29. Duckwall Fruit, Odell, OR
30. E. Brown & Sons, Inc., Milton-Freewater, OR
31. Evans Fruit Co., Inc., Yakima, WA
32. E.W. Brandt & Sons, Inc., Parker, WA
33. Frosty Packing Co., LLC, Yakima, WA
34. G&G Orchards, Inc., Yakima, WA
35. Garrett Ranches Packing, Wilder, ID
36. Gilbert Orchards, Inc., Yakima, WA
37. Gold Digger Apples, Inc., Oroville, WA
38. Hansen Fruit & Cold Storage Co., Inc., Yakima, WA
39. Henggeler Packing Co., Inc., Fruitland, ID
40. Highland Fruit Growers, Inc., Yakima, WA
41. HoneyBear Growers, Inc., (Brewster, WA)
42. Honey Bear Tree Fruit Co., LLC, Wenatchee, WA
43. Hood River Cherry Company, Hood River, OR
44. Ice Lakes LLC, E. Wenatchee, WA
45. JackAss Mt. Ranch, Pasco, WA
46. Jenks Bros Cold Storage Packing (Royal City, WA)
47. Kershaw Fruit & Cold Storage, Co., Yakima, WA
48. L&M Companies, Selah, WA
49. Larson Fruit Co., Selah, WA
50. Manson Growers Cooperative, Manson, WA
51. Matson Fruit Company, Selah, WA
52. McDougall & Sons, Inc., Wenatchee, WA
53. Monson Fruit Co.—Apple operations only, Selah, WA
54. Morgan's of Washington dba Double Diamond Fruit, Quincy, WA
55. Naumes, Inc., Medford, OR
56. Northern Fruit Company, Inc., Wenatchee, WA
57. Olympic Fruit Co., Moxee, WA
58. Oneonta Trading Corp., Wenatchee, WA
59. Orchard View Farms, Inc., The Dalles, OR
60. Pacific Coast Cherry Packers, LLC, Yakima, WA
61. Peshastin Hi-Up Growers, Peshastin, WA
62. Phillippi Fruit Company, Inc., Wenatchee, WA
63. Piepel Premium Fruit Packing, LLC, East Wenatchee, WA
64. Polehn Farm's Inc., The Dalles, OR
65. Price Cold Storage & Packing Co., Inc., Yakima, WA
66. Pride Packing Company, Wapato, WA
67. Quincy Fresh Fruit Co., Quincy, WA
68. Rainier Fruit Company, Selah, WA
69. Roche Fruit, Ltd., Yakima, WA
70. Ron Lefore, d/b/a Ron Lefore Apple Farms, Milton-Freewater, OR
71. Sage Fruit Company, L.L.C., Yakima, WA
72. Smith & Nelson, Inc., Tonasket, WA
73. Stadelman Fruit, L.L.C., Milton-Freewater, OR, and Zillah, WA
74. Stemilt Growers, LLC, Wenatchee, WA
75. Strand Apples, Inc., Cowiche, WA
76. Symms Fruit Ranch, Inc., Caldwell, ID
77. The Dalles Fruit Company, LLC, Bingen, WA
78. Underwood Fruit & Warehouse Co., Dallesport, WA
79. Valicoff Fruit Co., Inc., Wapato, WA
80. Valley Fruit III L.L.C., Wapato, WA
81. Washington Cherry Growers, Peshastin, WA
82. Washington Fruit & Produce Co., Yakima, WA
83. Western Sweet Cherry Group, LLC, Yakima, WA
84. Western Traders, LLC, East Wenatchee, WA
85. Whitby Farms, Inc. dba: Farm Boy Fruit Snacks LLC, Mesa, WA
86. Yakima Fresh, Yakima, WA
87. Yakima Fruit & Cold Storage Co., Yakima, WA
88. Zirkle Fruit Company, Selah, WA

Dated: April 5, 2016.

**Joseph E. Flynn,**

*Director, Office of Trade and Economic Analysis.*

[FR Doc. 2016-08390 Filed 4-11-16; 8:45 am]

**BILLING CODE 3510-DR-P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

#### Quarterly Update to Annual Listing of Foreign Government Subsidies on Articles of Cheese Subject to an In-Quota Rate of Duty

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**DATES:** *Effective Date:* April 12, 2016.

**FOR FURTHER INFORMATION CONTACT:** Stephanie Moore, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Ave. NW., Washington, DC 20230, telephone: (202) 482-3692.

**SUPPLEMENTARY INFORMATION:** Section 702 of the Trade Agreements Act of 1979 (as amended) (the Act) requires the Department of Commerce (the Department) to determine, in consultation with the Secretary of Agriculture, whether any foreign government is providing a subsidy with respect to any article of cheese subject to an in-quota rate of duty, as defined in section 702(h) of the Act, and to publish quarterly updates to the type and amount of those subsidies. We hereby provide the Department's quarterly update of subsidies on articles of cheese that were imported during the periods October 1, 2015, through December 31, 2015.

The Department has developed, in consultation with the Secretary of Agriculture, information on subsidies, as defined in section 702(h) of the Act, being provided either directly or indirectly by foreign governments on articles of cheese subject to an in-quota rate of duty. The appendix to this notice lists the country, the subsidy program or programs, and the gross and net amounts of each subsidy for which information is currently available. The Department will incorporate additional programs which are found to constitute subsidies, and additional information

on the subsidy programs listed, as the information is developed.

The Department encourages any person having information on foreign government subsidy programs which benefit articles of cheese subject to an in-quota rate of duty to submit such information in writing to the Assistant

Secretary for Enforcement and Compliance, U.S. Department of Commerce, 14th Street and Constitution Ave. NW., Washington, DC 20230.

This determination and notice are in accordance with section 702(a) of the Act.

Dated: April 5, 2016.

**Ronald K. Lorentzen,**  
*Acting Assistant Secretary for Enforcement and Compliance.*

**Appendix**

SUBSIDY PROGRAMS ON CHEESE SUBJECT TO AN IN-QUOTA RATE OF DUTY

Country	Program(s)	Gross <sup>1</sup> subsidy (\$/lb)	Net <sup>2</sup> subsidy (\$/lb)
28 European Union Member States <sup>3</sup>	European Union Restitution Payments	0.00	0.00
Canada	Export Assistance on Certain Types of Cheese	0.46	0.46
Norway	Indirect (Milk) Subsidy	0.00	0.00
	Consumer Subsidy	0.00	0.00
	Total	0.00	0.00
Switzerland	Deficiency Payments	0.00	0.00

<sup>1</sup> Defined in 19 U.S.C. 1677(5).

<sup>2</sup> Defined in 19 U.S.C. 1677(6).

<sup>3</sup> The 28 member states of the European Union are: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom.

[FR Doc. 2016-08389 Filed 4-11-16; 8:45 am]

BILLING CODE 3510-DS-P

**CORPORATION FOR NATIONAL AND COMMUNITY SERVICE**

**Sunshine Act Notice**

The Board of Directors of the Corporation for National and Community Service gives notice of the following meeting:

**DATE AND TIME:** Friday, April 22, 2016, 11:00 a.m.–12:15 p.m. (ET).

**PLACE:** Corporation for National and Community Service, 250 E Street SW., Suite 4026, Washington, DC 20525 (Please go to the first floor lobby reception area for escort).

**CALL-IN INFORMATION:** This meeting is available to the public through the following toll-free call-in number: 888-390-3401 conference call access code number 2572123. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and CNCS will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Replays are generally available one hour after a call ends. The toll-free phone number for the replay is 866-479-2459. TTY: 800-833-3722. The end replay date is May 6, 2016 at 10:59 p.m. (CT).

**STATUS:** Open.

**MATTERS TO BE CONSIDERED:**

I. Chair's Opening Comments

a. Call to Order, Welcome, and Preview of Today's Meeting Agenda

b. Introduction and Acknowledgements

c. Summary Status of Board Interaction

II. CEO Report

III. Guest Speaker: The September 11th National Day of Service and Remembrance

IV. Public Comments

V. Final Comments and Adjournment

Members of the public who would like to comment on the business of the Board may do so in writing or in person. Individuals may submit written comments to [dpremo@cns.gov](mailto:dpremo@cns.gov) subject line: APRIL 2016 CNCS BOARD MEETING by 4:00 p.m. (ET) on April 20, 2016. Individuals attending the meeting in person who would like to comment will be asked to sign-in upon arrival. Comments are requested to be limited to 2 minutes.

**REASONABLE ACCOMMODATIONS:** The Corporation for National and Community Service provides reasonable accommodations to individuals with disabilities where appropriate. Anyone who needs an interpreter or other accommodation should notify David Premo at [dpremo@cns.gov](mailto:dpremo@cns.gov) or 202-606-6717 by 5 p.m. (ET) on April 15, 2016.

**CONTACT PERSON FOR MORE INFORMATION:** Dave Premo, Program Support Specialist, Corporation for National and Community Service, 250 E Street SW., Washington, DC 20525. Phone: 202-606-6717. Fax: 202-606-3460. TTY: 800-833-3722. Email: [dpremo@cns.gov](mailto:dpremo@cns.gov).

Dated: April 8, 2016.

**Jeremy Joseph,**  
*General Counsel.*

[FR Doc. 2016-08548 Filed 4-8-16; 4:15 pm]

BILLING CODE 6050-28-P

**DEPARTMENT OF DEFENSE**

**Department of the Air Force**

**US Air Force Exclusive Patent License**

**AGENCY:** Department of the Air Force, Air Force Research Laboratory Information Directorate, Rome, New York, DOD.

**ACTION:** Notice of intent to issue an exclusive patent license.

**SUMMARY:** Pursuant to the provisions of part 404 of Title 37, Code of Federal Regulations, which implements Public Law 96-517, as amended, the Department of the Air Force announces its intention to grant The Curators of the University of Missouri, a public corporation of Missouri having a place of business at the Office of Technology Management and Industry Relations, 1601 S. Providence Road, #124, Columbia, Missouri 65211, an exclusive license in any right, title and interest the United States Air Force has in: In U.S. Patent No. 14/795,953 entitled "SYSTEM AND METHOD FOR STATIC AND MOVING OBJECT DETECTION", filed July 10, 2015.

**FOR FURTHER INFORMATION CONTACT:** An exclusive license for this patent will be granted unless a written objection is received within fifteen (15) days from the date of publication of this Notice.

Written objections should be sent to: Air Force Research Laboratory, Office of the Staff Judge Advocate, AFRL/RIJ, 26 Electronic Parkway, Rome, New York 13441-4514. Telephone: (315) 330-2087; Facsimile (315) 330-7583.

**Henry Williams Jr.,**

*Acting Air Force Federal Register Liaison Officer.*

[FR Doc. 2016-08378 Filed 4-11-16; 8:45 am]

**BILLING CODE 5001-10-P**

## DEPARTMENT OF EDUCATION

### Applications for New Awards; Advanced Placement Test Fee Program

**AGENCY:** Office of Elementary and Secondary Education, Department of Education.

**ACTION:** Notice.

#### Overview Information

##### *Advanced Placement Test Fee Program*

Notice inviting applications for new awards for fiscal year (FY) 2016.

Catalog of Federal Domestic Assistance (CFDA) Number: 84.330B.

#### **DATES:**

*Applications Available:* April 12, 2016.

*Deadline for Transmittal of Applications:* May 12, 2016.

*Deadline for Intergovernmental Review:* July 11, 2016.

#### **Full Text of Announcement**

##### **I. Funding Opportunity Description**

*Purpose of Program:* The Advanced Placement Test Fee (APTF) Program awards grants to State educational agencies (SEAs) to enable them to pay all or a portion of advanced placement test fees on behalf of eligible low-income students who (1) are enrolled in an advanced placement course; and (2) plan to take an advanced placement exam. The program is designed to increase the number of low-income students who take advanced placement tests and receive scores for which college academic credit is awarded.

**Program Authority:** The Elementary and Secondary Education Act of 1965 (ESEA), as amended by the No Child Left Behind Act of 2001 (NCLB) (20 U.S.C. 6531-6537).

**Note:** On December 10, 2015, the President signed into law the Every Student Succeeds Act (ESSA), Public Law 114-95, which reauthorized the ESEA, as amended by NCLB. Under section 5(c) of the ESSA, APTF Program grants awarded in FY 2016 and earlier years will operate in accordance with the requirements of the ESEA, as amended by NCLB.

*Applicable Regulations:* (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 79, 81, 82, 84, 97, 98, and 99. (b) The OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The regulations in 34 CFR part 299.

**Note:** The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian tribes.

##### **II. Award Information**

*Type of Award:* Discretionary grants.  
*Estimated Available Funds:*

\$28,483,000.

*Estimated Range of Awards:* \$13,235-\$10,757,186.

*Estimated Average Size of Awards:*

\$694,710.

*Estimated Number of Awards:* 41.

**Note:** The Department is not bound by any estimates in this notice.

*Project Period:* Up to 12 months.

##### **III. Eligibility Information**

1. *Eligible Applicants:* SEAs in any State, including the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and the freely associated states of the Republic of the Marshall Islands, the Federated States of Micronesia, and the Republic of Palau (subject to continued eligibility).

**Note:** For the purposes of this program, the Bureau of Indian Education in the U.S. Department of the Interior is treated as an SEA.

2.a. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

b. *Supplement-Not-Supplant:* This program involves supplement, not supplant, funding requirements. Section 1706 of the ESEA, as amended by NCLB, requires that grant funds provided under the APTF Program supplement, and not supplant, other non-Federal funds that are available to assist low-income individuals in paying for the cost of advanced placement test fees.

##### **IV. Application and Submission Information**

1. *Address to Request Application Package:* You can obtain an application

package via the Internet or from the program office.

To obtain a copy via the Internet, use the following address: <http://www2.ed.gov/programs/apfee/applicant.html>.

To obtain a copy from the program office, contact: Francisco Ramirez, U.S. Department of Education, 400 Maryland Avenue SW., Room 3E310, Washington, DC 20202-6200. Telephone: (202) 260-1541 or by email: [francisco.ramirez@ed.gov](mailto:francisco.ramirez@ed.gov).

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

Individuals with disabilities can obtain a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) by contacting the program contact person listed in this section.

2. *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.

3. *Submission Dates and Times:* Applications Available: April 12, 2016.

*Deadline for Transmittal of Applications:* May 12, 2016.

Applications for grants under this competition must be submitted electronically using the Grants.gov Apply site (Grants.gov). For information (including dates and times) about how to submit your application electronically, or in paper format by mail or hand delivery if you qualify for an exception to the electronic submission requirement, please refer to *Other Submission Requirements* in section IV of this notice.

We do not consider an application that does not comply with the deadline requirements.

Individuals with disabilities who need an accommodation or auxiliary aid in connection with the application process should contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice. If the Department provides an accommodation or auxiliary aid to an individual with a disability in connection with the application process, the individual's application remains subject to all other requirements and limitations in this notice.

*Deadline for Intergovernmental Review:* July 11, 2016.

4. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR

part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this competition.

5. *Funding Restrictions:* 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), the Government's primary registrant database;

c. Provide your DUNS number and TIN on your application; and

d. Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet at the following Web site: <http://fedgov.dnb.com/webform>. A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data you enter into the SAM database. Thus, if you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN. We strongly recommend that you register early.

**Note:** Once your SAM registration is active, it may be 24 to 48 hours before you can access the information in, and submit an application through, Grants.gov.

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS number is correct. Also note that you will need to update your registration

annually. This may take three or more business days.

Information about SAM is available at [www.SAM.gov](http://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](http://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 APTF Program, CFDA number 84.330B, must be submitted electronically using the Governmentwide Grants.gov Apply site at [www.Grants.gov](http://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 APTF Program at [www.Grants.gov](http://www.Grants.gov). You must search for the downloadable application package for this competition by the CFDA number's alpha suffix in your search (e.g., search for 84.330, not 84.330B).

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](http://www.G5.gov). In addition, for specific guidance and procedures for submitting an application through Grants.gov, please refer to the Grants.gov Web site at: [www.grants.gov/web/grants/applicants/apply-for-grants.html](http://www.grants.gov/web/grants/applicants/apply-for-grants.html).

- You will not receive additional point value because you submit your application in electronic format, nor will we penalize you if you qualify for an exception to the electronic submission requirement, as described elsewhere in this section, and submit your application in paper format.

- You must submit all documents electronically, including all information you typically provide on the following forms: The Application for Federal Assistance (SF 424), the Department of Education Supplemental Information for SF 424, Budget Information—Non-Construction Programs (ED 524), and all necessary assurances and certifications.

- You must upload any narrative sections and all other attachments to your application as files in a read-only, non-modifiable Portable Document Format (PDF). Do not upload an interactive or fillable PDF file. If you upload a file type other than a read-only, non-modifiable PDF (e.g., Word, Excel, WordPerfect, etc.) or submit a password-protected file, we will not review that material. Please note that this could result in your application not being considered for funding because the material in question—for example, the project narrative—is critical to a meaningful review of your proposal. For that reason it is important to allow yourself adequate time to upload all material as PDF files. The Department will not convert material from other formats to PDF.

- Your electronic application must comply with any page-limit requirements described in this notice.
- After you electronically submit your application, you will receive from Grants.gov an automatic notification of receipt that contains a Grants.gov tracking number. This notification indicates receipt by Grants.gov only, not receipt by the Department. Grants.gov will also notify you automatically by email if your application met all the Grants.gov validation requirements or if there were any errors (such as submission of your application by someone other than a registered Authorized Organization Representative, or inclusion of an attachment with a file name that contains special characters). You will be given an opportunity to correct any errors and resubmit, but you must still meet the deadline for submission of applications.

Once your application is successfully validated by Grants.gov, the Department will retrieve your application from Grants.gov and send you an email with a unique PR/Award number for your application.

These emails do not mean that your application is without any disqualifying errors. While your application may have been successfully validated by Grants.gov, it must also meet the Department's application requirements as specified in this notice and in the application instructions. Disqualifying errors could include, for instance, failure to upload attachments in a read-only, non-modifiable PDF; failure to submit a required part of the application; or failure to meet applicant eligibility requirements. It is your responsibility to ensure that your submitted application has met all of the Department's requirements.

- We may request that you provide us original signatures on forms at a later date.

*Application Deadline Date Extension in Case of Technical Issues with the Grants.gov System:* If you are experiencing problems submitting your application through Grants.gov, please contact the Grants.gov Support Desk, toll free, at 1-800-518-4726. You must obtain a Grants.gov Support Desk Case Number and must keep a record of it.

If you are prevented from electronically submitting your application on the application deadline date because of technical problems with the Grants.gov system, we will grant you an extension until 4:30:00 p.m., Washington, DC time, the following business day to enable you to transmit your application electronically or by hand delivery. You also may mail your application by following the mailing instructions described elsewhere in this notice.

If you submit an application after 4:30:00 p.m., Washington, DC time, on the application deadline date, please contact the person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice and provide an explanation of the technical problem you experienced with Grants.gov, along with the Grants.gov Support Desk Case Number. We will accept your application if we can confirm that a technical problem occurred with the Grants.gov system and that the problem affected your ability to submit your application by 4:30:00 p.m., Washington, DC time, on the application deadline date. We will contact you after we determine whether your application will be accepted.

**Note:** The extensions to which we refer in this section apply only to the unavailability of, or technical problems with, the Grants.gov system. We will not grant you an extension if you failed to fully register to submit your application to Grants.gov before the application deadline date and time or if the technical problem you experienced is unrelated to the Grants.gov system.

*Exception to Electronic Submission Requirement:* You qualify for an exception to the electronic submission requirement, and may submit your application in paper format, if you are unable to submit an application through the Grants.gov system because—

- You do not have access to the Internet; or
- You do not have the capacity to upload large documents to the Grants.gov system; and
- No later than two weeks before the application deadline date (14 calendar days or, if the fourteenth calendar day

before the application deadline date falls on a Federal holiday, the next business day following the Federal holiday), you mail or fax a written statement to the Department, explaining which of the two grounds for an exception prevents you from using the Internet to submit your application.

If you mail your written statement to the Department, it must be postmarked no later than two weeks before the application deadline date. If you fax your written statement to the Department, we must receive the faxed statement no later than two weeks before the application deadline date.

Address and mail or fax your statement to: Francisco Ramirez, U.S. Department of Education, 400 Maryland Avenue SW., Room 3E310, Washington, DC 20202-6200. FAX: (202) 260-8969.

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 84.330B), LBJ Basement Level 1, 400 Maryland Avenue SW., Washington, DC 20202-4260.

You must show proof of mailing consisting of one of the following:

- (1) A legibly dated U.S. Postal Service postmark.
- (2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.
- (3) A dated shipping label, invoice, or receipt from a commercial carrier.
- (4) Any other proof of mailing acceptable to the Secretary of the U.S. Department of Education.

If you mail your application through the U.S. Postal Service, we do not accept either of the following as proof of mailing:

- (1) A private metered postmark.
- (2) A mail receipt that is not dated by the U.S. Postal Service.

**Note:** The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, you should check with your local post office.

We will not consider applications postmarked after the application deadline date.

### *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 84.330B), 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. *Review and Selection Process:* The Department intends to fund, at some level, all applications that meet the requirements for approving applications described in the application package for this program and that demonstrate a need for new or additional funds to pay advanced placement exam fees on behalf of low-income students for school year 2015-16.

Under section 1707(1) of the ESEA, as amended by NCLB, “advanced placement test” means an advanced placement test administered by the College Board or approved by the Secretary. For FY 2016, advanced placement tests administered by the College Board include Advanced Placement (AP) Seminar and AP Research under the College Board’s new AP Capstone program. In addition, for FY 2016, the Secretary approves the following advanced placement tests:

(a) Diploma Programme tests administered by the International Baccalaureate Organization (IBO);

(b) Advanced Subsidiary (AS) Level tests administered by Cambridge International Examinations, including Global Perspectives and Research Test; and

(c) Advanced (A) Level tests administered by Cambridge International Examinations; including Global Perspectives and Research Test.

For FY 2016, the Department expects to award approximately \$28,483,000 in new grants under this program. Based on the anticipated number of applications and other available information (including any expected fee reductions for low-income students), the Department expects this amount to be sufficient to pay all but \$15 of the cost of each advanced placement exam taken by low-income students.

Accordingly, SEAs may use APTF Program funds to cover a portion of the cost of each approved advanced placement exam taken by low-income students in school year 2015-16, as follows: (a) Up to \$38 for each AP test administered by the College Board that is not an AP Seminar or AP Research exam under the College Board’s AP Capstone program; (b) up to \$85 for each AP Seminar test administered by the College Board under its AP Capstone program; (c) up to \$85 for each AP Research test administered by the College Board under its AP Capstone program; (d) up to \$98 for each Diploma Programme test administered by the IBO; (e) up to \$69.10 for each AS Level test administered by Cambridge International Examinations that is not a Global Perspectives and Research exam; (f) up to \$112.90 for each A Level test administered by Cambridge International Examinations that is not a Global Perspectives and Research exam; (g) up to \$134.73 for each AS Level Global Perspectives and Research test administered by Cambridge International Examinations; and (h) up to \$226.50 for each A Level Global Perspectives and Research test administered by Cambridge International Examinations.

**Note:** APTF Program funds may not be used to pay registration fees on behalf of low-income students. Therefore, advanced placement test registration fees, including the student registration fees charged by the IBO, are not allowable costs under this program.

Further information and instructions on how to request funds for school year 2015-16 are included in the application package for this competition.

Also, in determining whether to approve an application for a new award (including the amount of the award) from an applicant with a current grant under this program, the Department will consider the amount of any unexpended funds under the existing grant and the applicant’s use of funds under previous APTF Program grant awards.

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).

2. *Risk Assessment and Special Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this competition the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may impose special conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

### **VI. Award Administration Information**

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to

comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to [www.ed.gov/fund/grant/apply/appforms/appforms.html](http://www.ed.gov/fund/grant/apply/appforms/appforms.html).

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

4. *Performance Measures*: Under the Government Performance and Results Act of 1993, the Department has developed five performance measures to evaluate the overall effectiveness of the APTF Program: (1) The number of advanced placement tests taken by low-income public school students nationally; (2) The number of advanced placement tests taken by minority (Hispanic, Black, Native American) public school students nationally; (3) The percentage of advanced placement tests passed (for AP tests, scores of 3–5) by low-income public school students nationally; (4) The number of advanced placement tests passed (for AP tests, scores of 3–5) by low-income public school students nationally; and (5) The cost per passing advanced placement test taken by a low-income public school student. The information provided by grantees in their final performance reports will be one source of data for the measures. Other sources of data include the College Board, IBO, and Cambridge International Examinations.

## VII. Agency Contact

### FOR FURTHER INFORMATION CONTACT:

Francisco Ramirez, U.S. Department of Education, 400 Maryland Avenue SW., Room 3E310, Washington, DC 20202–6200. Telephone: (202) 260–1541 or by email: [francisco.ramirez@ed.gov](mailto:francisco.ramirez@ed.gov).

If you use a TDD or a TTY, call the FRS, toll free, at 1–800–877–8339.

## VIII. Other Information

*Accessible Format*: Individuals with disabilities can obtain this document

and a copy of the application package in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT** in section VII of this notice.

*Electronic Access to This Document*: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: [www.gpo.gov/fdsys](http://www.gpo.gov/fdsys). At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or PDF. To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: [www.federalregister.gov](http://www.federalregister.gov). Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: April 7, 2016.

**Ann Whalen**,

*Senior Advisor to the Secretary Delegated the Duties of Assistant Secretary for the Office of Elementary and Secondary Education.*

[FR Doc. 2016–08396 Filed 4–11–16; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF EDUCATION

[Docket No.: ED–2016–ICCD–0012]

### Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Indian Education Professional Development Grants Program: GPRA and Service Payback Data Collection

**AGENCY**: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

**ACTION**: Notice.

**SUMMARY**: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a revision of an existing information collection.

**DATES**: Interested persons are invited to submit comments on or before May 12, 2016.

**ADDRESSES**: To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED–2016–ICCD–0012. Comments submitted in response to this notice should be

submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E–105, Washington, DC 20202–4537. **FOR FURTHER INFORMATION CONTACT**: For specific questions related to collection activities, please contact John Cheek, 202–401–0274.

**SUPPLEMENTARY INFORMATION**: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

*Title of Collection*: Indian Education Professional Development Grants Program: GPRA and Service Payback Data Collection.

*OMB Control Number*: 1810–0698.

*Type of Review*: A revision of an existing information collection.

*Respondents/Affected Public*: State, Local, and Tribal Governments.

*Total Estimated Number of Annual Responses*: 1,740.

*Total Estimated Number of Annual Burden Hours*: 2,728.



*Abstract:* The Indian Education Professional Development (IEPD) Grants program provides grants to prepare and train Indians (*i.e.*, American Indians/Alaska Natives) to serve as teachers and administrators. The specific goals of the IEPD program are to: (1) Increase the number of qualified individuals in professions that serve American Indians/Alaska Natives; (2) provide training to qualified American Indians/Alaska Natives to become teachers, administrators, teacher aides, social workers, and ancillary education personnel; and (3) improve the skills of those qualified American Indians/Alaska Natives who already serve in these capacities. Individuals trained under this program must perform work related to their training and that benefits American Indian/Alaska Native people, or repay all or a prorated portion of the assistance received under the program.

This data collection serves three purposes: First, data from three sources (grantees, project participants, and employers) are necessary to assess the performance of the IEPD program on its Government Performance Results Act (GPRA) measures. Second, data from all three sources are necessary to determine if IEPD participants are fulfilling the terms of their service/cash payback requirements. Finally, budget and project-specific performance data are collected from IEPD grantees for project-monitoring and compliance information. The forms and protocols contained in this package include the Grantee Reporting Form, the Participant Training Information and Employment Reporting Form, and the Employment Verification Form.

Dated: April 7, 2016.

**Stephanie Valentine,**

*Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.*

[FR Doc. 2016-08347 Filed 4-11-16; 8:45 am]

**BILLING CODE 4000-01-P**

## FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-0384]

### 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 June 13, 2016. 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 to [PRA@fcc.gov](mailto:PRA@fcc.gov) and to [Nicole.Ongele@fcc.gov](mailto: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:* 3060-0384.

*Title:* Sections 64.901, 64.904 and 64.905, Auditor's Attestation and Certification.

*Form Number:* N/A.

*Type of Review:* Extension of a currently approved collection.

*Respondents:* Business or other for-profit entities.

*Number of Respondents and Responses:* 1 respondent, 1 response.

*Estimated Time per Response:* 5-250 hours.

*Obligation to Respond:* Required to obtain or retain benefits. Statutory authority is contained in sections 1, 4, 201-205, 215, and 218-220 of the Communications Act of 1934, as

amended, 47 U.S.C. 151, 154, 201-205, 215, and 218-220.

*Frequency of Response:* On-occasion, biennial, and annual reporting requirements.

*Total Annual Burden:* 255 hours.

*Total Annual Cost:* \$1,200,000.

*Privacy Act Impact Assessment:* No impact(s).

*Nature of Extent of Confidentiality:* This collection does not address information of a confidential nature.

*Needs and Uses:* Section 64.904(a) states that each incumbent LEC required to file a cost allocation manual shall elect to either have an attest engagement performed by an independent auditor every two years, covering the prior two year period, or have a financial audit performed by an independent auditor biennially. In either case, the initial engagement shall be performed in the calendar year after the carrier is first required to file a cost allocation manual. See section 64.904(a)-(c). Instead of requiring mid-sized carriers to incur the expense of a biennial attestation engagement, they now file a certification with the Commission stating that they are in compliance with 47 CFR 64.901 of the Commission's rules, which sets out the rules regarding allocation of costs. The certification must be signed, under oath, by an officer of the incumbent LEC, and filed with the Commission on an annual basis. Such certification of compliance represents a less costly means of enforcing compliance with our cost allocation rules. See 47 CFR 64.905 of the Commission's rules. The requirements are imposed to ensure that the carriers are properly complying with Commission rules. They serve as an important aid in the Commission's monitoring program. Section 64.905 requires mid-sized LECs to file a certification with the Commission stating that they are complying with section 64.901. The certification must be signed, under oath, by an officer of the mid-sized LEC, and filed with the Commission on an annual basis at the time that the mid-sized incumbent LEC files the annual reports required by section 43.21(e)(2).

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary, Office of the Secretary.*

[FR Doc. 2016-08374 Filed 4-11-16; 8:45 am]

**BILLING CODE 6712-01-P**

**FEDERAL COMMUNICATIONS COMMISSION**

[OMB 3060–0439, 3060–0665, and 3060–0973]

**Information Collections 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 June 13, 2016. 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](mailto:PRA@fcc.gov) and to [Cathy.Williams@fcc.gov](mailto: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: 3060–0439.

*Title:* Section 64.201, Regulations Concerning Indecent Communications by Telephone.

*Form Number:* N/A.

*Type of Review:* Extension of a currently approved collection.

*Respondents:* Business or other for-profit entities; Individuals or households.

*Number of Respondents and Responses:* 10,200 respondents; 30,000 responses.

*Estimated Time per Response:* 166 hours (10 minutes average per response).

*Frequency of Response:* On occasion reporting requirements; Third party disclosure.

*Obligation to Respond:* Required to obtain or retain benefits. The statutory authority for the information collection requirements is found at Section 223 of the Communications Act of 1934, as amended (the Act), 47 U.S.C. 223, Obscene or Harassing Telephone Calls in the District of Columbia or in Interstate or Foreign Communications.

*Total Annual Burden:* 4,980 hours.

*Total Annual Cost:* None.

*Nature and Extent of Confidentiality:* Confidentiality is an issue to the extent that individuals and households provide personally identifiable information, which is covered under the FCC's updated system of records notice (SORN), FCC/CGB–1, "Informal Complaints, Inquiries, and Request for Dispute Assistance"; published in the **Federal Register** on August 15, 2014, at 79 FR 48152, and became effective on September 24, 2014.

*Privacy Impact Assessment:* The FCC completed a Privacy Impact Assessment (PIA) on June 28, 2007. The PIA may be reviewed at [http://www.fcc.gov/omd/privacyact/Privacy\\_Impact\\_Assessment.html](http://www.fcc.gov/omd/privacyact/Privacy_Impact_Assessment.html). The FCC is in the process of updating the PIA to incorporate various revisions made to the SORN.

*Needs and Uses:* Under section 223 of the Act, common carriers are required, to the extent technically feasible, to prohibit access to obscene or indecent communications from the telephone of a subscriber who has not previously requested such access in writing, if the carrier collects charges from subscribers for such communications. 47 CFR 64.201 implements section 223 of the Act, and also include the following information collection requirements: (1) Adult message service providers notify their carriers in writing of the nature of their service; and (2) A provider of adult message services request that its carriers identify these services as such in bills to their subscribers. The information requirements are imposed on carriers,

and on adult message service providers and those who solicit their services, to ensure that minors and anyone who has not consented to access such material are denied access to such material in adult message services.

*OMB Control Number:* 3060–0665.

*Title:* Section 64.707, Public Dissemination of Information by Providers of Operator Services.

*Form Number:* N/A.

*Type of Review:* Extension of a currently approved collection.

*Respondents:* Business or other for-profit entities.

*Number of Respondents and Responses:* 448 respondents; 448 responses.

*Estimated Time per Response:* 4 hours (average per response).

*Frequency of Response:* On occasion reporting requirements; Third party disclosure.

*Obligation to Respond:* Required to obtain or retain benefits. The statutory authority citation for the information collection requirements is found at Section 226 of the Act, 47 U.S.C 226.

*Total Annual Burden:* 1,792 hours.

*Total Annual Cost:* \$44,800.

*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 (PII) from individuals.

*Privacy Impact Assessment:* No impact(s).

*Needs and Uses:* Pursuant to 47 CFR 64.707, providers of operator services must regularly publish and make available at no cost to requesting consumers written materials that describe any recent changes in operator services and choices available to consumers. Consumers use the information to increase their knowledge of the choices available to them in the operator services marketplace.

*OMB Control Number:* 3060–0973.

*Title:* Section 64.1120(e), Verification of Orders for Telecommunications Service.

*Form Number:* N/A.

*Type of Review:* Extension of a currently approved collection.

*Respondents:* Businesses or other for-profit entities.

*Number of Respondents and Responses:* 50 respondents; 150 responses.

*Estimated Time per Response:* 1 to 5 hours (average per response).

*Frequency of Response:* On occasion reporting requirements; Third-party disclosure requirement.

*Obligation to Respond:* Required to obtain or retain benefits. The statutory authority citation for the information

collection requirements is found at Section 258 of the Act, 47 U.S.C. 258.

*Total Annual Burden:* 350 hours.

*Total Annual Cost:* None.

*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 (PII) from individuals.

*Privacy Impact Assessment:* No impact(s).

*Needs and Uses:* Pursuant to 47 CFR 64.1120 (e), a carrier acquiring all or part of another carrier's subscriber base without obtaining each subscriber's authorization and verification will file a letter specifying certain information with the Commission, in advance of the transfer, and it will also certify that the carrier will comply with required procedures, including giving advance notice to the affected subscribers.

These streamlined carrier change rules balance the protection of consumers' interests with ensuring that the Commission's rules do not unnecessarily inhibit routine business transactions.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary, Office of the Secretary.*

[FR Doc. 2016-08377 Filed 4-11-16; 8:45 am]

**BILLING CODE 6712-01-P**

## FEDERAL DEPOSIT INSURANCE CORPORATION

### Notice of Termination; 10494 Syringa Bank, Boise, Idaho

The Federal Deposit Insurance Corporation (FDIC), as Receiver for 10494 Syringa Bank, Boise, Idaho (Receiver) has been authorized to take all actions necessary to terminate the receivership estate of Syringa Bank (Receivership Estate); the Receiver has made all dividend distributions required by law.

The Receiver has further irrevocably authorized and appointed FDIC-Corporate as its attorney-in-fact to execute and file any and all documents that may be required to be executed by the Receiver which FDIC-Corporate, in its sole discretion, deems necessary; including but not limited to releases, discharges, satisfactions, endorsements, assignments and deeds.

Effective April 1, 2016, the Receivership Estate has been terminated, the Receiver discharged, and the Receivership Estate has ceased to exist as a legal entity.

Dated: April 6, 2016.

Federal Deposit Insurance Corporation.

**Robert E. Feldman,**

*Executive Secretary.*

[FR Doc. 2016-08343 Filed 4-11-16; 8:45 am]

**BILLING CODE 6714-01-P**

## FEDERAL DEPOSIT INSURANCE CORPORATION

### Notice of Termination; 10169 St. Stephen State Bank, St. Stephen, Minnesota

The Federal Deposit Insurance Corporation (FDIC), as Receiver for 10169 St. Stephen State Bank, St. Stephen, Minnesota (Receiver) has been authorized to take all actions necessary to terminate the receivership estate of St. Stephen State Bank (Receivership Estate); the Receiver has made all dividend distributions required by law.

The Receiver has further irrevocably authorized and appointed FDIC-Corporate as its attorney-in-fact to execute and file any and all documents that may be required to be executed by the Receiver which FDIC-Corporate, in its sole discretion, deems necessary; including but not limited to releases, discharges, satisfactions, endorsements, assignments and deeds.

Effective April 01, 2016, the Receivership Estate has been terminated, the Receiver discharged, and the Receivership Estate has ceased to exist as a legal entity.

Dated: April 6, 2016.

Federal Deposit Insurance Corporation.

**Robert E. Feldman,**

*Executive Secretary.*

[FR Doc. 2016-08342 Filed 4-11-16; 8:45 am]

**BILLING CODE 6714-01-P**

## FEDERAL DEPOSIT INSURANCE CORPORATION

### Notice of Termination; 10468 Westside Community Bank, University Place, Washington

The Federal Deposit Insurance Corporation (FDIC), as Receiver for 10468 Westside Community Bank, University Place, Washington (Receiver) has been authorized to take all actions necessary to terminate the receivership estate of Westside Community Bank (Receivership Estate); the Receiver has made all dividend distributions required by law.

The Receiver has further irrevocably authorized and appointed FDIC-Corporate as its attorney-in-fact to execute and file any and all documents that may be required to be executed by the Receiver which FDIC-Corporate, in

its sole discretion, deems necessary; including but not limited to releases, discharges, satisfactions, endorsements, assignments and deeds.

Effective April 1, 2016, the Receivership Estate has been terminated, the Receiver discharged, and the Receivership Estate has ceased to exist as a legal entity.

Dated: April 7, 2016.

Federal Deposit Insurance Corporation.

**Robert E. Feldman,**

*Executive Secretary.*

[FR Doc. 2016-08357 Filed 4-11-16; 8:45 am]

**BILLING CODE 6714-01-P**

## FEDERAL ELECTION COMMISSION

### Sunshine Act Meetings

**AGENCY:** Federal Election Commission.

**DATE & TIME:** Thursday, April 14, 2016 at 10:00 a.m.

**PLACE:** 999 E Street NW., Washington, DC (ninth floor).

**STATUS:** This meeting will be open to the public.

**ITEMS TO BE DISCUSSED:**

Correction and Approval of Minutes for February 11, 2016

Correction and Approval of Minutes for February 25, 2016

Draft Advisory Opinion 2016-01: Ethiq, Inc.

Draft Advisory Opinion 2016-02: Enable Midstream Services, LLC

Draft Final Rule and Explanation and Justification for Technical Amendments to 2015 CFR

Proposed Modifications to Program for Requesting Consideration of Legal Questions by the Commission

Proposed Statement of Policy Regarding the Public Disclosure of Closed Enforcement Files

Rulemaking Proposals:

Motion to Open a Rulemaking to Assist Those Accepting Corporate Contributions or Making Corporate Expenditures in Complying with Existing Campaign Finance Law

Motion Regarding Foreign National Rulemaking

Management and Administrative Matters

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Shawn Woodhead Werth, Secretary and Clerk, at (202) 694-1040, at least 72 hours prior to the meeting date.

**PERSON TO CONTACT FOR INFORMATION:**  
Judith Ingram, Press Officer, Telephone:  
(202) 694-1220.

**Shawn Woodhead Werth,**

*Secretary and Clerk of the Commission.*

[FR Doc. 2016-08417 Filed 4-8-16; 11:15 am]

**BILLING CODE 6715-01-P**

## FEDERAL RESERVE SYSTEM

### Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than April 27, 2016.

A. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *Deanna Alfred; Elizabeth Dippel Masser; Ted Christian Masser, as custodian for the TUTMA accounts for Ted Henry Masser and Katherine Elizabeth Masser; Kurt Andrew Alfred; Lauren Elizabeth Alfred, all of Brenham, Texas; and Corby Wade Alfred, Austin, Texas; all as members of the Alfred/Dippel/Voelter family group, and collectively acting as a group in concert; to retain voting shares of Brenham Bancshares, Inc., and thereby indirectly retain voting shares of Brenham National Bank, both in Brenham, Texas.*

Board of Governors of the Federal Reserve System, April 7, 2016.

**Michael J. Lewandowski,**

*Associate Secretary of the Board.*

[FR Doc. 2016-08340 Filed 4-11-16; 8:45 am]

**BILLING CODE 6210-01-P**

## FEDERAL RESERVE SYSTEM

### Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval,

pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The 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 May 6, 2016.

A. Federal Reserve Bank of Dallas (Robert L. Triplett III, Senior Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *WestStar Bank Holding Company, Inc., El Paso, Texas; to merge with First Fabens Bancorporation, Inc., and thereby indirectly acquire First National Bank, both in Fabens, Texas.*

Board of Governors of the Federal Reserve System, April 7, 2016.

**Michael J. Lewandowski,**

*Associate Secretary of the Board.*

[FR Doc. 2016-08341 Filed 4-11-16; 8:45 am]

**BILLING CODE 6210-01-P**

## FEDERAL TRADE COMMISSION

### Agency Information Collection Activities; Submission for OMB Review; Comment Request

**AGENCY:** Federal Trade Commission.

**ACTION:** Notice and request for comment.

**SUMMARY:** In compliance with the Paperwork Reduction Act (PRA) of 1995, the FTC is seeking public comments on its request to OMB for a three-year extension of the current PRA clearance for the information collection requirements contained in the Mail, Internet, or Telephone Order

Merchandise Rule (MITOR). This clearance expires on April 30, 2016.

**DATES:** Comments must be received by May 12, 2016.

**ADDRESSES:** Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "Mail, Internet, or Telephone Order Merchandise Trade Regulation Rule: FTC File No. R511929" on your comment, and file your comment online at <https://ftcpublic.commentworks.com/ftc/mitorpra2> by following the instructions on the Web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC-5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex J), Washington, DC 20024.

### FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of the proposed information requirements should be addressed to Jock Chung, Attorney, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW., Washington, DC 20580, (202) 326-2984.

### SUPPLEMENTARY INFORMATION:

*Title:* Mail, Internet, or Telephone Order Merchandise Rule (MITOR or Rule), 16 CFR part 435.

*OMB Control Number:* 3084-0106.

*Type of Review:* Extension of a currently approved collection.

*Abstract:* Generally, the MITOR requires a merchant to: (1) Have a reasonable basis for any express or implied shipment representation made in soliciting the sale (if no express time period is promised, the implied shipment representation is 30 days); (2) notify the consumer and obtain the consumer's consent to any delay in shipment; and (3) make prompt and full refunds when the consumer exercises a cancellation option or the merchant is unable to meet the Rule's other requirements.

The notice provisions in the Rule require a merchant who is unable to ship within the promised shipment time or 30 days to notify the consumer of a revised date and his or her right to cancel the order and obtain a prompt refund. Delays beyond the revised shipment date also trigger a notification requirement to consumers. When the

MITOR requires the merchant to make a refund and the consumer has paid by credit card, the Rule also requires the merchant to notify the consumer either that any charge to the consumer's charge account will be reversed or that the merchant will take no action that will result in a charge.

On January 19, 2016, the Commission sought comment on the information collection requirements in MTOR. See 81 FR 2860. The Commission received two comments but neither one addressed the issues raised by the public comment request. As required by OMB regulations, 5 CFR part 1320, the FTC is providing this second opportunity for public comment.

**Likely Respondents:** Businesses engaged in the sale of merchandise by mail or by telephone.

**Estimated Annual Hours Burden:** 1,953,840 hours.

**Third Party Disclosure:** [(33,267 established businesses × 50 hours) + (1,263 new entrants × 230 hours) = 1,953,840 hours.

**Estimated Annual Cost Burden:** \$44,879,705, which is derived from 1,953,840 hours × \$22.97/hour.<sup>1</sup>

#### Request for Comment

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before May 12, 2016. Write "Mail, Internet, or Telephone Order Merchandise Trade Regulation Rule: FTC File No. R511929" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Web site, at <http://www.ftc.gov/os/publiccomments.shtm>. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card

number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which is . . . privileged or confidential," as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you are required to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c). Your comment will be kept confidential only if the FTC General Counsel grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comment online, or to send it to the Commission by courier or overnight service. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublish.commentworks.com/ftc/mitorpra2>, by following the instructions on the Web-based form. If this Notice appears at <http://www.regulations.gov>, you also may file a comment through that Web site.

If you file your comment on paper, write "Mail, Internet, or Telephone Order Merchandise Trade Regulation Rule: FTC File No. R511929" on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC-5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before May 12, 2016. You can find more

information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at <http://www.ftc.gov/ftc/privacy.shtm>.

Comments on the information collection requirements subject to review under the PRA should also be submitted to OMB. If sent by U.S. mail, address comments to: Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission, New Executive Office Building, Docket Library, Room 10102, 725 17th Street NW., Washington, DC 20503. Comments sent to OMB by U.S. postal mail, however, are subject to delays due to heightened security precautions. Thus, comments instead should be sent by facsimile to (202) 395-5167.

**Christian S. White,**

*Deputy General Counsel.*

[FR Doc. 2016-08369 Filed 4-11-16; 8:45 am]

**BILLING CODE 6750-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Emergency Funding for Puerto Rico Department of Health, Zika Virus Outbreak

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

**ACTION:** This notice announces the Centers for Disease Control and Prevention's (CDC) intent to fund the Puerto Rico Department of Health with Prevention and Public Health Funds (PPHF).

PPHF 2016: Epidemiology and Laboratory Capacity Program—Emergency Funding for Puerto Rico Department of Health, Zika virus Outbreak for Infectious Diseases (ELC)—financed solely by Prevention and Public Health Funds.

FOA Number: CDC-RFA-CK14-140103CONTPPHF2016.

**SUMMARY:** The U.S. Centers for Disease Control and Prevention (CDC) is providing \$3,700,000 in urgent funding through the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement to the Puerto Rico Department of Health (PRDOH) to combat the current outbreak of Zika virus.

#### Project Description

Puerto Rico is experiencing an approximate doubling of confirmed Zika

<sup>1</sup> This is the mean hourly income for workers in sales and related occupations according to the latest figures from the Department of Commerce's Bureau of Labor Statistics. See Table 1, National employment and wage data from the Occupational Employment Statistics survey by occupation, May 2015, at <http://www.bls.gov/news.release/ocwage.t01.htm>.

virus cases per week—they are unique in the total number of cases, the level of local transmission, and the presence of the Zika-carrying vector. Currently, the PR DOH cannot sufficiently address necessary aspects of the outbreak response without additional support. In addition to equipment and supplies necessary for the increased testing for Zika virus, funds awarded to PRDOH will be used to support additional epidemiology and laboratory staff critical to the response efforts.

#### *Prevention Fund Reporting*

**Requirements:** This award requires the grantee to complete projects or activities which are funded under the Prevention and Public Health Fund (PPHF) (Section 4002 of Pub. L. 111–148) and to report on use of PPHF funds provided through this award. Information from these reports will be made available to the public.

Grantees awarded a grant, cooperative agreement, or contract from such funds with a value of \$25,000 or more shall produce reports on a semi-annual basis with a reporting cycle of January 1–June 30 and July 1–December 31; and email such reports to the CDC Web site (template and point of contact to be provided after award) no later than 20 calendar days after the end of each reporting period (*i.e.* July 20 and January 20, respectively). Grantee reports must reference the NoA number and title of the grant, and include a summary of the activities undertaken and identify any sub-awards (including the purpose of the award and the identity of each sub-recipient).

**Responsibilities for Informing Sub-recipients:** Grantees agree to separately identify each sub-recipient, document the execution date sub-award, date(s) of the disbursement of funds, the Federal award number, any special CFDA number assigned for PPHF fund purposes, and the amount of PPHF funds. When a grantee awards PPHF funds for an existing program, the information furnished to sub-recipients shall distinguish the sub-awards of incremental PPHF funds from regular sub-awards under the existing program.

**DATES:** Effective date is April 12, 2016.

**ADDRESSES:** Alvin Shultz, MSPH, Division of Preparedness and Emerging Infectious, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Atlanta, GA 30333, Phone: 404–639–7028, E-Mail: [Ashultz@cdc.gov](mailto:Ashultz@cdc.gov).

**FOR FURTHER INFORMATION CONTACT:** Alvin Shultz, MSPH, Division of Preparedness and Emerging Infectious, National Center for Emerging and

Zoonotic Infectious, Diseases Centers for Disease Control and Prevention, 1600 Clifton Road NE., Atlanta, GA 30333. Phone: 404–639–7028. E-Mail: [Ashultz@cdc.gov](mailto:Ashultz@cdc.gov).

Dated: March 25, 2016.

**Terrance Perry,**

*Director, Office of Grants Services, Centers for Disease Control and Prevention.*

[FR Doc. 2016–08318 Filed 4–11–16; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30 Day–16–0217]

#### Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk

Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

#### Proposed Project

NCHS Vital Statistics Training Application (OMB Control No. 0920–0217, exp. 5/31/2016)—Revision—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

#### *Background and Brief Description*

In the United States, legal authority for the registration of vital events, *i.e.*, births, deaths, marriages, divorces, fetal deaths, and induced terminations of pregnancy, resides individually with the States (as well as cities in the case of New York City and Washington, DC) and Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. These governmental entities are the full legal proprietors of vital records and the information contained therein. As a result of this State authority, the collection of registration-based vital statistics at the national level, referred to as the U.S. National Vital Statistics System (NVSS), depends on a cooperative relationship between the States and the Federal government. This data collection, authorized by 42 U.S.C. 242k, has been carried out by NCHS since it was created in 1960.

NCHS assists in achieving the comparability needed for combining data from all States into national statistics, by conducting a training program for State and local vital statistics staff to assist in developing expertise in all aspects of vital registration and vital statistics. The training offered under this program includes courses for registration staff, statisticians, and coding specialists, all designed to bring about a high degree of uniformity and quality in the data provided by the States. This training program is authorized by 42 U.S.C. 242b, section 304(a).

NCHS notifies State and local vital registration officials, as well as Canadian counterparts, about upcoming training. Individual candidates for training then submit an application form including name, address, occupation, and other relevant information.

In this revision, the application for the Vital Statistics Training is being updated to capture additional logistical information. The proposed changes include the addition of two questions (1) to identify the training personnel as either State or locally-based and (2) to

determine if the registrant has previously attended the training. And if so, when? Likewise, the information listed for the NCHS contact person has been updated.

NCHS is requesting a three-year OMB clearance to collect the necessary information using these training application forms. The total estimated annualized burden hours are 30. There

is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
State, Local Health department and vital health Employees.	Annual Survey Training Needs .....	60	1	15/60
State, Local Health department and vital health Employees.	NCHS Vital Statistics Training Application ....	60	1	15/60

**Leroy A. Richardson,**  
 Chief, Information Collection Review Office,  
 Office of Scientific Integrity, Office of the  
 Associate Director for Science, Office of the  
 Director, Centers for Disease Control and  
 Prevention.  
 [FR Doc. 2016-08297 Filed 4-11-16; 8:45 am]  
 BILLING CODE 4163-18-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifiers: CMS-R-153 and CMS-R-284]

**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 May 12, 2016.

**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:* Medicaid Drug Use Review (DUR) Program; *Use:* States must provide for a review of drug therapy before each prescription is filled or delivered to a Medicaid patient. This review includes screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Pharmacists must make a reasonable effort to obtain, record, and maintain Medicaid patient profiles. These profiles must reflect at least the patient's name, address, telephone number, date of birth/age, gender, history, e.g., allergies, drug reactions, list of medications, and pharmacist's comments relevant to the individual's drug therapy.

The State must conduct RetroDUR which provides for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, inappropriate or medically unnecessary care. Patterns or trends of drug therapy problems are identified and reviewed to determine the need for intervention activity with pharmacists and/or physicians. States may conduct interventions via telephone, correspondence, or face-to-face contact.

Annual reports are submitted to CMS for the purposes of monitoring compliance and evaluating the progress of States' DUR programs. The information submitted by States is

reviewed and results are compiled by CMS in a format intended to provide information, comparisons and trends related to States' experiences with DUR. The States benefit from the information and may enhance their programs each year based on State reported innovative practices that are compiled by CMS from the DUR annual reports. *Form Number:* CMS-R-153 (OMB control number: 0938-0659); *Frequency:* Yearly, quarterly, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 510; *Total Annual Hours:* 20,808. (For policy questions regarding this collection contact Renee Hilliard at 410-786-2991.)

**2. Type of Information Collection**  
*Request:* Revision of a currently approved collection. *Title of Information Collection:* Medicaid Statistical Information System (MSIS) and Transformed—Medicaid Statistical Information System (T-MSIS); *Use:* The data reported in MSIS/T-MSIS are used by federal, state, and local officials, as well as by private researchers and corporations to monitor past and projected future trends in the Medicaid program. These data provide the only national level information available on enrollees, beneficiaries, and expenditures. They also provide the only national level information

available on Medicaid utilization. This information is the basis for analyses and for cost savings estimates for the Department's cost sharing legislative initiatives to Congress. The collected data are also crucial to our actuarial forecasts. *Form Number:* CMS-R-284 (OMB control number: 0938-0345); *Frequency:* Quarterly and monthly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 804; *Total Annual Hours:* 8,040. (For policy questions regarding this collection contact Camiel Rowe at 410-786-0069.)

Dated: April 5, 2016.  
**William N. Parham, III,**  
 Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2016-08116 Filed 4-11-16; 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:* Child Care and Development Fund Financial Report (ACF 696) for States and Territories.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF-696 .....	56	4	5	1,120

*Estimated Total Annual Burden Hours:* 1,120.

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

*OMB No.:* 0970-0163.  
*Description:* States and Territories use the Financial Report Form ACF-696 to report Child Care and Development Fund (CCDF) expenditures. Authority to collect and report this information is found in section 658G of the Child Care and Development Block Grant Act of 1990, as revised. In addition to the Program Reporting Requirements set forth in 45 CFR part 98, subpart H, the regulations at 45 CFR 98.65(g) and 98.67(c)(1) authorize the Secretary to require financial reports as necessary.

The form provides specific data regarding claims and provides a mechanism for States to request Child Care grant awards and to certify the availability of State matching funds. Failure to collect this data would seriously compromise ACF's ability to monitor Child Care and Development Fund expenditures. This information is also used to estimate outlays and may be used to prepare ACF budget submissions to Congress.

ACF has not made substantive revisions to the reporting form itself, but has revised the accompanying instructions to provide more detailed guidance to assist grantees with completing the form.

*Respondents:* States and Territories.

comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**  
 Reports Clearance Officer.  
 [FR Doc. 2016-08263 Filed 4-11-16; 8:45 am]  
**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

*Title:* Responding to Intimate Violence in Relationship programs (RIViR)

*OMB No.:* New Collection



*Description:* The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) is proposing a data collection as part of the “Responding to Intimate Violence in Relationship programs” (RIViR) study. This notice addresses testing of intimate partner violence (IPV) and teen dating violence (TDV) screener/protocols, to be conducted with approximately 1,200 participants from approximately six Healthy Marriage and Relationship Education (HMRE) grantees funded by the Office of Family Assistance (OFA).

There is little consensus on how HMRE programs should address IPV or

TDV in their programs. To date, no IPV or TDV screening tools have been empirically tested among HMRE program participants. The objective of the proposed data collection is to test and validate IPV and TDV screening instruments among HMRE program participants. Findings from this data collection will be used to develop practical, responsive guidance on IPV and TDV screening and surrounding protocols for HMRE programs.

Data collection will entail testing eight screening instruments: Six closed-ended screening instruments (three for IPV, three for TDV), and two open-ended instruments (one for IPV, one for

TDV). It is anticipated that each participant will engage in four rounds of data collection, one round for each IPV or TDV instrument, at least two weeks apart. Data collection is expected to occur from Winter 2016/2017 through Spring 2017.

*Respondents:* HMRE grantee program participants: 600 Youth (approximately ages 14–18) will participate in the TDV screener testing and 600 adults (ages 18 and older) will participate in the IPV screener testing.

ANNUAL BURDEN ESTIMATES

Instrument	Total/annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Adult Closed-ended IPV Screening Tool #1	600	1	.25	150
Adult Closed-ended IPV Screening Tool #2	600	1	.25	150
Adult Closed-ended IPV Screening Tool #3	600	1	.25	150
Adult Open-ended IPV Screening Tool	600	1	.5	300
Youth Closed-ended TDV Screening Tool #1	600	1	.25	150
Youth Closed-ended TDV Screening Tool #2	600	1	.25	150
Youth Closed-ended TDV Screening Tool #3	600	1	.25	150
Youth Open-ended TDV Screening Tool	600	1	.5	300

*Estimated Total Annual Burden Hours:* 1,500.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or

other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Robert Sargis,**  
*ACF Certifying Officer.*  
 [FR Doc. 2016–08363 Filed 4–11–16; 8:45 am]  
**BILLING CODE 4184–73–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**National Child Care Hotline and Web site; Comment request; Correction**

**AGENCY:** Administration for Children and Families, Department of Health and Human Services.

**ACTION:** Comment request; correction.

**SUMMARY:** The Administration for Children and Families published a document in the **Federal Register** on March 8, 2016, requesting comments on a National toll-free hotline and Web site for child care. The document contained an incorrect email address for responses. Because the email address was incorrect, the Administration for Children and Families is extending the deadline for submission of comments as well.

**FOR FURTHER INFORMATION CONTACT:**  
 Paula Bendl Smith, 202–401–5616.

**Corrections**

(1) In the **Federal Register** of March 8, 2016, in FR Doc. 81–12105, on page 12105, in the right-hand column, correct the **ADDRESSES** caption to read:

**ADDRESSES:** Submit comments to [NWHcomment@acf.hhs.gov](mailto:NWHcomment@acf.hhs.gov).

(2) In the **Federal Register** of March 8, 2016, in FR Doc. 81–12105, on page 12105, in the right-hand column, correct the **DATES** caption to read:

**DATES:** The deadline for receipt of comments is midnight, April 15, 2016.

Dated: April 6, 2016.

**Shannon Rudisill,**  
*Associate Deputy Assistant Secretary for Early Childhood Development.*

[FR Doc. 2016–08283 Filed 4–11–16; 8:45 am]

**BILLING CODE 4184–43–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-E-2345]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; ADEMPAS

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for ADEMPAS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

**DATES:** Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by June 13, 2016.

Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 11, 2016. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you

do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2014-E-2345 for "Determination of Regulatory Review Period for Purposes of Patent Extension; ADEMPAS." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access

the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product ADEMPAS (riociguat). ADEMPAS is indicated for treatment of adults with persistent/recurrent Chronic Thromboembolic

Pulmonary Hypertension (CTEPH) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class; and treatment of pulmonary arterial hypertension to improve exercise capacity, improve WHO functional class, and to delay clinical worsening. Subsequent to this approval, the USPTO received a patent term restoration application for ADEMPAS (U.S. Patent No. 7,173,037) from Bayer Intellectual Property GmbH, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 19, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of ADEMPAS represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

## II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for ADEMPAS is 2,394 days. Of this time, 2,151 days occurred during the testing phase of the regulatory review period, while 243 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* March 22, 2007. FDA has verified the Bayer Intellectual Property GmbH claim that March 22, 2007, is the date the investigational new drug application (IND) became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* February 8, 2013. FDA has verified the applicant's claim that the new drug application (NDA) for ADEMPAS (NDA 204819) was initially submitted on February 8, 2013.

3. *The date the application was approved:* October 8, 2013. FDA has verified the applicant's claim that NDA 204819 was approved on October 8, 2013.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,317 days of patent term extension.

## III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <http://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: April 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–08337 Filed 4–11–16; 8:45 am]

BILLING CODE 4164–01–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2014–N–1904]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Comparing Food Safety Knowledge, Attitude and Behavior Among English-Dominant Hispanics, Spanish-Dominant Hispanics, and Other Consumers

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. **DATES:** Fax written comments on the collection of information by May 12, 2016.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX:

202–395–7285, or emailed to [aira\\_submission@omb.eop.gov](mailto:aira_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910—New and title “Comparing Food Safety Knowledge, Attitude and Behavior Among English-dominant Hispanics, Spanish-dominant Hispanics, and Other Consumers.” Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Comparing Food Safety Knowledge, Attitude and Behavior Among English-Dominant Hispanics, Spanish-Dominant Hispanics, and Other Consumers—OMB Control Number 0910—NEW

### I. Background

We conduct research and educational and public information programs relating to food safety and nutrition issued in our broad statutory authority, set forth in section 1003(b)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 393(b)(2)), to protect the public health by ensuring that foods are “safe, wholesome, sanitary, and properly labeled,” and in section 1003(d)(2)(C) of the FD&C Act (21 U.S.C. 393(d)(2)(C)), to conduct research relating to foods, drugs, cosmetics, devices and tobacco products.

Our current food safety education and outreach programs and materials generally are developed and provided for the English-speaking population in the United States (U.S.) (Ref. 1). To better protect public health and to help consumers practice safe food handling, we need empirical data on how different population groups understand, perceive and practice food safety and food handling. An emerging and important demographic trend in the United States is the increase in Hispanics. Recent estimates suggest that Hispanics (defined as those who identify themselves as of Hispanic or Latino origin) are the largest and fastest growing minority group in the nation; the proportion of the U.S. population that was Hispanic was 14 percent in 2005 and is projected to increase to 29 percent in 2050 (Ref. 2).

Data from the Centers for Disease Control and Prevention (CDC) indicate that, in the past two decades, Hispanics were one of the population groups that often experienced higher incidence rates (per 100,000 population) of bacterial causes of foodborne illness than Caucasians (Ref. 3). These bacterial causes include *Campylobacter*, *Listeria monocytogenes* (*Listeria*), *Shigella*, and *Salmonella*. While some Hispanics living in the United States use the English language exclusively or more often than Spanish (English-dominant Hispanics), other U.S. Hispanics predominantly use the Spanish language in their daily lives (Spanish-dominant Hispanics) (Ref. 4). Since most U.S. food labels, including safe food handling instructions, are in English, Spanish-dominant Hispanics' understanding and use of safe food handling instructions may differ from that of English-dominant Hispanics and of non-Hispanics who use English exclusively. In addition, Hispanics may have certain food handling practices that may increase their risk of foodborne illness (Ref. 5).

FDA needs an understanding of how different population groups perceive and behave in terms of food safety and food handling to inform development of

possible measures that we may take to better protect public health and to help consumers practice safe food handling. FDA is aware of no consumer research on a nationwide level on how different population groups understand, perceive and practice food safety and food handling. This study is intended to provide initial answers to research questions such as whether and how much Spanish-dominant Hispanics, English-dominant Hispanics, and English-speaking non-Hispanics differ in their knowledge, attitude, and behavior toward food safety and food handling and the role that demographic and other factors may play in any differences.

The proposed study will use a Web-based instrument to collect information from 3,000 adult members in online consumer panels maintained by a contractor. The study plans to randomly select 1,000 panel members in each of three groups: Spanish-dominant Hispanics, English-dominant Hispanics, and English-speaking non-Hispanics. Both English and Spanish questionnaires will be used, as appropriate. The study plans to include topics such as: (1) Food safety knowledge and attitude; and (2) food handling and consumption practice. To

help us understand the data, the study will also collect information on respondents' background, including, but not limited to, health status and demographic characteristics, such as age, gender, education, and income, and degree of acculturation among Hispanic respondents using a measure developed by Marin et al. (Ref. 6).

The study is part of our continuing effort to protect the public health. We will not use the results of the study to develop population estimates. We plan to use the results of the study to develop follow-up quantitative and qualitative research to gauge the prevalence and extent of differences in food safety knowledge and behaviors between the three mentioned population groups. We plan to use the results of the follow-up research to help inform the design of effective education and outreach initiatives aimed at helping reduce the risk of foodborne illness for the general U.S. population as well as Hispanics.

In the **Federal Register** of November 28, 2014 (79 FR 70875), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cognitive interview screener .....	72	1	72	0.083 (5 minutes) .....	6
Cognitive interview .....	9	1	9	1.5 (90 minutes) .....	14
Pretest invitation .....	1,440	1	1,440	0.033 (2 minutes) .....	48
Pretest .....	180	1	180	0.25 (15 minutes) .....	45
Study invitation .....	24,000	1	24,000	0.033 (2 minutes) .....	792
Study .....	3,000	1	3,000	0.25 (15 minutes) .....	750
<b>Total</b> .....					<b>1,655</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimates on prior experience with research that is similar to this proposed study. We will use a cognitive interview screener with 72 individuals to recruit prospective interview participants. We estimate that it will take a screener respondent approximately 5 minutes (0.083 hours) to complete the cognitive interview screener, for a total of 5.976 hours, rounded to 6 hours. We will conduct cognitive interviews with nine participants. We estimate that it will take a participant approximately 90 minutes to complete the interview, for a total of 13.5 hours, rounded to 14 hours. We also plan to conduct a pretest to identify and resolve potential survey

administration problems. We will send a pretest invitation to 1,440 prospective pretest participants and estimate that it will take a respondent approximately 2 minutes (0.033 hours) to complete the invitation, for a total of 47.52 hours, rounded to 48 hours. We will administer the pretest with 180 participants and estimate that it will take a participant 15 minutes (0.25 hours) to complete the pretest, for a total of 45 hours. We will send a study invitation to 24,000 prospective participants and estimate that it will take a respondent approximately 2 minutes (0.033 hours) to complete the invitation, for a total of 792 hours. We will administer the study with 3,000

participants and estimate that it will take a participant 15 minutes (0.25 hours) to complete the study, for a total of 750 hours. The total estimated burden for all the study activities is 1,655 hours; this estimate is 9 hours higher than that shown in the 60-day notice due to revised hours for cognitive interviews, from 30 minutes (0.5 hours) to 90 minutes (1.5 hours) each interview.

**II. References**

1. U.S. Food and Drug Administration. "Foodborne Illness & Contaminants." June 9, 2014. (<http://www.fda.gov/Food/FoodborneIllnessContaminants/default.htm>).
2. Passel, J.S. and C. D'Vera. "U.S. Population Projections: 2005–2050." Pew

Research Center. February 11, 2008. (<http://pewhispanic.org/files/reports/85.pdf>).

3. Quinlan, J.J. "Foodborne Illness Incidence Rates and Food Safety Risks for Populations of Low Socioeconomic Status and Minority Race/Ethnicity: A Review of the Literature." *International Journal of Environmental Research and Public Health* 10(8): 3634–3652, 2013.

4. Taylor, P., M.H. Lopez, J. Martínez and G. Velasco. "Language Use Among Latinos." Pew Research Center. April 4, 2012. (<http://www.pewhispanic.org/2012/04/04/iv-language-use-among-latinos/>).

5. Henley, S.C., S.E. Stein and J.J. Quinlan. "Identification of Unique Food Handling Practices That Could Represent Food Safety Risks for Minority Consumers." *Journal of Food Protection* 75: 2050–2054, 2012.

6. Marin, G., F. Sabogal, B.V. Marin, *et al.* "Development of a Short Acculturation Scale for Hispanics." *Hispanic Journal of Behavioral Sciences* 9(2): 183–205, 1987.

Dated: April 6, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–08332 Filed 4–11–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2016–N–1101]

#### EMD Serono; Withdrawal of Approval of a New Drug Application for LUVÉRIS

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is withdrawing approval of a new drug application (NDA) for LUVÉRIS (lutropin alpha for injection) held by EMD Serono, One Technology Place, Rockland, MA 02370. EMD Serono has voluntarily requested that approval of this application be withdrawn, thereby waiving its opportunity for a hearing.

**DATES:** Effective April 12, 2016.

**FOR FURTHER INFORMATION CONTACT:**

Emily Helms Williams, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6280, Silver Spring, MD 20993–0002, 301–796–3381.

**SUPPLEMENTARY INFORMATION:** FDA approved LUVÉRIS (lutropin alpha for injection) on October 8, 2004, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. LUVÉRIS is indicated for concomitant administration with GONAL–F (follitropin alfa for injection) for stimulation of follicular development in

infertile hypogonadotropic hypogonadal women with profound luteinizing hormone deficiency. In a letter dated April 30, 2012, EMD Serono requested that FDA withdraw approval of NDA 021322 for LUVÉRIS under § 314.150(c). In that letter, EMD Serono noted that, as had been previously discussed with the Agency, it was not feasible to complete a trial that the company had agreed to at the time of approval under subpart H. By letter dated December 8, 2014, FDA notified EMD Serono that, when studies that are required as a condition of approval under the Agency's accelerated approval regulations are not completed, the approval of an application is withdrawn according to the procedures set forth in §§ 314.530 and 314.150(d) rather than under § 314.150(c). FDA requested that EMD Serono submit a new withdrawal request under § 314.150(d).

Following additional correspondence, by letter dated July 23, 2015, EMD Serono requested that FDA withdraw approval of NDA 021322 for LUVÉRIS under § 314.150(d) because a postmarketing study that was required as a condition of approval under subpart H was not completed. Because that study was required to verify and describe the clinical benefit of the drug product, the clinical benefit of LUVÉRIS has not been confirmed, and it has not been established to be safe and effective. In its July 23, 2015, letter, EMD Serono waived any opportunity for a hearing otherwise provided under §§ 314.150 and 314.530. FDA responded by letter dated September 2, 2015, acknowledging EMD Serono's request that FDA withdraw approval of LUVÉRIS under § 314.150(d). FDA also acknowledged that EMD Serono waived its opportunity for a hearing.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) and § 314.150(d), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of NDA 021322, and all amendments and supplements thereto, is withdrawn (see DATES). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: April 6, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–08336 Filed 4–11–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2012–N–0560]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by May 12, 2016.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910–0582. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable—OMB Control Number 0910–0582—Extension

FDA's investigational device regulations are intended to encourage the development of new, useful devices in a manner that is consistent with public health, safety, and compliant with ethical standards. Investigators should have freedom to pursue the least burdensome means of accomplishing this goal. However, to ensure that the balance is maintained between product

development and the protection of public health, safety, and ethical standards, FDA has established human subject protection regulations addressing requirements for informed consent and institutional review board (IRB) review that apply to all FDA-regulated clinical investigations involving human subjects. In particular, informed consent requirements further both safety and ethical considerations by allowing potential subjects to consider both the physical and privacy risks they face if they agree to participate in a trial.

Under FDA regulations, clinical investigations using human specimens conducted in support of premarket submissions to FDA are considered human subject investigations (see 21 CFR 812.3(p)). Many investigational device studies are exempt from most provisions of part 812, Investigational Device Exemptions, under 21 CFR

812.2(c)(3), but FDA's regulations for the protection of human subjects (21 CFR parts 50 and 56) apply to all clinical investigations that are regulated by FDA (see 21 CFR 50.1, 21 CFR 56.101, 21 U.S.C. 360j(g)(3)(A), and 21 U.S.C. 360j(g)(3)(D)).

FDA regulations do not contain exceptions from the requirements of informed consent on the grounds that the specimens are not identifiable or that they are remnants of human specimens collected for routine clinical care or analysis that would otherwise have been discarded. Nor do FDA regulations allow IRBs to decide whether or not to waive informed consent for research involving leftover or unidentifiable specimens.

In a level 1 guidance document, entitled "Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually

Identifiable," issued under the Good Guidances Practices regulation, 21 CFR 10.115, FDA outlines the circumstances in which it intends to exercise enforcement discretion as to the informed consent regulations for clinical investigators, sponsors, and IRBs.

The recommendations of the guidance impose a minimal burden on industry. FDA estimates that 700 studies will be affected annually. Each study will result in one annual record, estimated to take 4 hours to complete. This results in a total recordkeeping burden of 2,800 hours (700 × 4 = 2,800).

In the **Federal Register** of October 23, 2015 (80 FR 64422), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

The FD&C Act section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
520(g) .....	700	1	700	4	2,800

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 6, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-08329 Filed 4-11-16; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2016-N-0832]

**Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed; Opportunity for Hearing**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of opportunity for hearing.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM), is proposing to withdraw approval of all new animal drug applications (NADAs) providing for use of carbadox in medicated swine feed. This action is based on CVM's determination that the use of carbadox under the approved conditions of use results in residues of carcinogenic concern in the edible tissues of the treated swine.

**DATES:** Phibro Animal Health Corp. may submit a request for a hearing by May 12, 2016. Submit all data and analysis upon which the request for a hearing relies by July 11, 2016.

**ADDRESSES:** The request for a hearing may be submitted by Phibro Animal Health Corp. by either of the following methods:

*Electronic Submission*

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments to submit your request for hearing. Your request for a hearing submitted electronically, including any attachments to the request for hearing, to <http://www.regulations.gov> will be posted to the docket unchanged.

*Written/Paper Submission*

- *Mail/Hand delivery/Courier (for written/paper request for a hearing):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Because your request for a hearing will be made public, you are solely responsible for ensuring that your request does not include any confidential information that you may not wish to be publicly posted, such as

confidential business information, e.g., a manufacturing process. The request for a hearing must include the Docket No. FDA-2016-N-0832 for "Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed; Opportunity for Hearing." The request for a hearing will be placed in the docket and publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Phibro Animal Health Corp. may submit all data and analysis upon which the request for a hearing relies in the same manner as the request for a hearing except as follows:

- **Confidential Submissions**—To submit any data and analyses with confidential information that you do not wish to be made publicly available, submit your data and analyses only as a written/paper submission. You should submit two copies total of all data and analysis. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of any decisions on this matter. The second copy, which will have the claimed confidential

information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov> or available at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Submit both copies to the Division of Dockets Management. Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law.

**Comments Submitted by Other Interested Parties:** For all comments submitted by other interested parties you may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA-2016-N-0832 for “Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed; Opportunity for Hearing.”

Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Vernon Toelle, Center for Veterinary Medicine (HFV-230), 7519 Standish Pl., Rockville, MD 20855, 240-276-9200.

#### SUPPLEMENTARY INFORMATION:

##### I. Approved NADAs for Use of Carbadox in Swine Feed

Carbadox, a quinoxaline derivative, is a synthetic organic acid antimicrobial. Currently, there are three approved NADAs for use of carbadox in

medicated swine feed, either by itself or in combination with other approved new animal drugs. Phibro Animal Health Corp. (Phibro), 65 Challenger Rd., Ridgefield Park, NJ 07660, is currently the sponsor of all three approved NADAs.

Carbadox is marketed as a Type A medicated article used to manufacture complete Type C medicated feeds that are administered ad libitum to swine. Carbadox is indicated for the control of dysentery and bacterial enteritis, and for growth promotion. A tolerance of 30 parts per billion (ppb)<sup>1</sup> has been established for residues of quinoxaline-2-carboxylic acid (QCA), the marker residue, in liver of swine (21 CFR 556.100).

The following three NADAs are approved for the use of carbadox:

NADA 041-061, originally approved in 1972 (37 FR 20683, October 3, 1972), provides for the use of MECADOX 10 (carbadox) Type A medicated article to manufacture single-ingredient Type C medicated swine feeds for the following conditions of use:

- Carbadox at 10 to 25 grams per ton (g/ton) of feed for increased rate of weight gain and improved feed efficiency; and
- Carbadox at 50 g/ton of feed for control of swine dysentery (vibronic dysentery, bloody scours, or hemorrhagic dysentery); for control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); and for increased rate of weight gain and improved feed efficiency.

Currently, the withdrawal period for these uses of carbadox is 42 days (§ 558.115(d)(1)(ii) and (d)(2)(ii) (21 CFR 558.115(d)(1)(ii) and (d)(2)(ii))).

NADA 092-955, originally approved in 1975 (40 FR 45164, October 1, 1975), provides for the use of MECADOX 10 (carbadox) Type A medicated article with BANMINTH (pyrantel tartrate) Type A medicated article to manufacture two-way, combination drug Type C medicated swine feeds for the following conditions of use:

- Carbadox at 50 g/ton of feed plus pyrantel tartrate at 96 g/ton of feed for control of swine dysentery (vibronic dysentery, bloody scours, or hemorrhagic dysentery); for control of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis*); as an aid in the prevention of migration and establishment of large roundworm

<sup>1</sup> For consistency and readability throughout this document, concentrations are reported as parts per billion even though original references may report some concentrations as parts per trillion (ppt).

(*Ascaris suum*) infections; and as an aid in the prevention of establishment of nodular worm (*Oesophagostomum*) infections.

The withdrawal period for the use of this drug combination is 70 days (§ 558.115(d)(3)(ii)).

NADA 141–211, originally approved in 2004 (69 FR 51173, August 18, 2004), provides for the use of MECADOX 10 (carbadox) Type A medicated article with TERRAMYCIN 50, TERRAMYCIN 100, or TERRAMYCIN 200

(oxytetracycline) Type A medicated articles to manufacture two-way, combination drug Type C medicated swine feeds for the following conditions of use:

- Carbadox at 10 to 25 g/ton of feed plus oxytetracycline at levels in feed to deliver 10 mg carbadox per pound of body weight for treatment of bacterial enteritis caused by *Escherichia coli* and *S. choleraesuis* susceptible to oxytetracycline; for treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline; and for increased rate of weight gain and improved feed efficiency.

The withdrawal period for the use of this animal drug combination is 42 days (§ 558.115(d)(4)(ii)).

## II. Basis for Withdrawal of Approval

CVM is providing notice of an opportunity for a hearing (NOOH) on a proposal to withdraw approval of the NADAs providing for use of carbadox in medicated swine feeds. New evidence regarding carcinogenic residues in edible tissues of swine treated with carbadox raises serious questions about the human food safety of the drug. Grounds for withdrawing carbadox are twofold. First, new evidence demonstrates that the Delaney Clause in section 512(d) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b), which requires that no residue of a carcinogenic drug can be found in any edible portion of the animal after slaughter, applies because the Diethylstilbestrol (DES) Proviso exception is no longer met (see, Section III.C). Second, new evidence demonstrates that carbadox is not shown to be safe under the General Safety Clause (section 512(e)(1)(B) of the FD&C Act).

During the review of a supplemental application to NADA 041–061 approved in January 1998, CVM made the following conclusions about the drug: (1) The parent compound carbadox is rapidly metabolized and carcinogenic residues of the drug are not identifiable in any edible tissues beyond 72 hours post dosing; (2) remaining unextracted

residues of carbadox are noncarcinogenic residues related to the noncarcinogenic metabolite QCA; and (3) QCA is a reliable marker residue for carbadox and its metabolites (Ref. 1).

Since the evaluation of information submitted by the sponsor in that supplemental application, CVM has become aware of new information that calls into question the basis for its previous conclusions. As described more fully in Section V., this includes new residue depletion data presented to the Joint FAO/WHO Expert Committee on Food Additives (JECFA)<sup>2</sup> in 2003 that shows that when the marker residue QCA reaches the approved tolerance of 30 ppb in liver, concentrations of the carcinogen desoxycarbadox (DCBX) in the liver would be approximately 4 times higher than the concentration that would be considered safe (Ref. 2 at pp. 16–17). In addition, the new residue depletion data presented to JECFA in 2003 call into question CVM's previously held conclusion that the unextracted residues of carbadox at the withdrawal period are noncarcinogenic compounds related to the QCA metabolite (Ref. 1). The Agency treats the unidentified residues—metabolites of a carcinogenic parent drug with demonstrated carcinogenic metabolites—as carcinogenic. Therefore, the drug is not shown to be safe under the General Safety Clause and the Delaney Clause applies to the drug, because the DES Proviso exception is no longer met.

Continued approval of carbadox would expose humans to concentrations of total residues of carcinogenic concern that are approximately 30 times higher (for the approved 42-day withdrawal period) or 11 times higher (for the approved 70-day withdrawal period) than the 0.915 ppb concentration of total residues of carcinogenic concern in liver that would be considered safe (Ref. 3 at p. 17, Table 8). Moreover, the sponsor has not identified an appropriate marker and analytical method to assure that residues of carcinogenic concern are below the level at which the residues present in the total human diet present no

significant increase in the risk of cancer to people (the S<sub>0</sub>).

In addition to the new information presented to JECFA (Ref. 2), publications by Boison, et al., in 2009 (Ref. 4) and Baars, et al., in 1990 (Ref. 5) that were recently provided to CVM by the sponsor call into question the previous conclusion that QCA is an appropriate marker and that all residues of carcinogenic concern deplete within 72 hours after dosing.

The new evidence from the 2003 JECFA report (Ref. 2) in conjunction with the publications by Boison, et al., in 2009 (Ref. 4) and Baars, et al., in 1991 (Ref. 6), erode the scientific justification for, and validity of, conclusions previously made about the drug in 1998. Based on this new information, evaluated together with the information available at the time of the approvals, CVM has determined that the drug is not shown to be safe under the General Safety Clause and that the Delaney Clause applies to the drug, because the DES Proviso exception is no longer met. Therefore, CVM proposes to withdraw approval of all NADAs for new animal drugs containing carbadox.

## III. Legal Context of the Proposed Action and Grounds for Withdrawal

### A. The Determination of Safety in Section 512

Carbadox, for each of its uses in swine, is a new animal drug as defined in section 201(v) of the FD&C Act (21 U.S.C. 321(v)). As such, under sections 301, 501, 512, 571, and 572 of the FD&C Act (21 U.S.C. 331, 351, 360b, 360ccc, 360ccc–1), the drug cannot be legally introduced or delivered for introduction into interstate commerce in the absence of an NADA approval, a conditional approval, or an animal drug indexing. The requirements for approval of an NADA are set out in section 512(d)(2)(A) of the FD&C Act. Section 512(b)(1)(A) of the FD&C Act requires that a new animal drug must be shown to be safe and effective for its intended uses. Section 201(u) of the FD&C Act provides that “safe” as used in section 512 of the FD&C Act “has reference to the health of man or animal.” The determination of safety requires CVM to consider, among other relevant factors, “the probable consumption of such drug and any substance formed in or on food because of the use of such drug . . .” (section 512(d)(2)(A) of the FD&C Act). Accordingly, CVM must consider not only safety of the new animal drug to the target animal, but also the safety to humans of substances formed in or on food as a result of the use of the new animal drug.

<sup>2</sup> JECFA is an independent committee of international scientific experts administered jointly by the United Nations Food and Agriculture Organization (FAO) and the World Health Organization (WHO) for the purpose of providing independent scientific advice to the FAO, WHO, and member countries. It has been meeting since 1956 specifically to evaluate the safety of food additives, including the animal drug residues in edible tissues. See <http://www.codexalimentarius.org/scientific-basis-for-codex/jecfa/en/> and [http://www.who.int/foodsafety/areas\\_work/chemical-risks/jecfa/en/](http://www.who.int/foodsafety/areas_work/chemical-risks/jecfa/en/).



“Safe,” in the context of human food safety, means a “reasonable certainty of no harm.” The definition is derived from language in H. Rep. No. 85–2284, at 4–5 (1958), defining the term “safe” as it appears in section 409 of the FD&C Act, which governs food additives (21 U.S.C. 348). Until passage of the Animal Drug Amendments of 1968 (Pub. L. 90–399) (the 1968 amendments), substances formed in or on food due to the use of animal drugs in food-producing animals were regulated under the food additive provisions in section 409 of the FD&C Act. The 1968 amendments consolidated all of the existing statutory authorities related to animal drugs into section 512 of the FD&C Act, and the legislative history shows that the consolidation in no way changed the authorities with respect to the regulation of new animal drugs (S. Rep. No. 90–1308, at 1 (1968)). During the new animal drug application review process, CVM has consistently applied the “reasonable certainty of no harm” standard in determining the safety of substances formed in or on food as a result of the use of a new animal drug in a food-producing animal.

In order to determine whether a new animal drug meets this standard, section 512(b)(1)(G)–(H) of the FD&C Act requires that whenever a drug may result in residues of the drug or its metabolites in food, an application must include not only full reports of investigations to show that the use of the drug is safe, but also a description of practicable methods for monitoring food to assure that there are no unsafe residues in human food attributable to the drug use, and a demonstration that the conditions of use are adequate to assure there are no unsafe residues.

In sum, under section 512(d)(2) of the FD&C Act, the Agency is required, in the evaluation of the supporting safety data, among other things, to consider:

- The probable consumption of such drug and of any substance formed in or on food because of the use of such drug (*i.e.*, probable human consumption of residues including the parent drug and its metabolites);
- The cumulative effect on man or animal of such drug, taking into account any chemically or pharmacologically related substance, *i.e.*, toxicological effects of the compounds comprising the residues; and
- Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data (*i.e.*, establishing “safe” levels of residues using appropriate safety factors to

extrapolate animal data on cumulative effects to humans).

When establishing the human food safety of a noncarcinogenic new animal drug used in food-producing animals, CVM establishes a no observed effect level (NOEL) for the residues of that drug in edible tissues—namely, the highest dose of the drug that does not produce the most sensitive treatment-related toxic endpoint in test animals (Ref. 7). From the NOEL, CVM uses safety factors to calculate an acceptable daily intake, and consumption factors to calculate the safe concentration of residues in a particular edible tissue (Ref. 7 at p. 15; section 512(b)(1)(H) of the FD&C Act).

Carbadox is both a genotoxic<sup>3</sup> and mutagenic carcinogen in animals. In the case of a genotoxic carcinogenic drug, establishing the human food safety of the compound via a NOEL is not feasible, therefore human food safety of carcinogenic compounds is ordinarily evaluated by using linear, low-dose extrapolation to evaluate the maximum concentration of total residues of carcinogenic concern that can be present in the total human diet without a significant increase in the risk of cancer to the human consumer (section 512(d)(1)(I) of the FD&C Act; 21 CFR 500.82 and 500.84). In both cases, the safe residue level of the drug is determined through an evaluation of the relevant data relating to the three factors listed above; *viz.*, the probable consumption of the drug residue and its cumulative effect as determined through all relevant safety factors (section 512(d)(2) of the FD&C Act).

#### *B. Grounds for Withdrawal Under the FD&C Act*

Section 512(e)(1)(B) of the FD&C Act provides grounds for withdrawal of approval of an NADA if new evidence not contained in an approved application or not available to the Secretary of Health and Human Services until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be

<sup>3</sup> Genotoxic refers to chemicals that react with DNA or chromosomes to cause damage. When the damage is not repaired and the effect is a heritable change (cell to cell or parent to offspring), it is also termed mutagenic. Thus not all genotoxic chemicals are mutagenic, but all mutagenic chemicals are genotoxic. Uncorrected mutagenesis is thought to be a key step in the development of cancer. “Mechanisms of Toxicity,” in *Casarett & Doull’s Toxicology: The Basic Science of Poisons*, edited by Klassen, C.D., 8th Ed., pp. 49–123, 2013.

safe for use under the conditions of use upon the basis of which the application was approved or that subparagraph (I) of paragraph (1) of subsection (d) applies to such drug. The Secretary of Health and Human Services has delegated this authority to the Commissioner of Food and Drugs. See FDA Staff Manual Guide 1410.10 (April 11, 2014).

In other words, grounds for withdrawal exist where new evidence shows either that the Delaney Clause applies to the drug (“subparagraph (I) of paragraph (1) of subsection (d)”) or that the drug is not shown to be safe under the approved conditions of use (the General Safety Clause). As explained further, new evidence demonstrates that carbadox meets both grounds for withdrawal.

In a proceeding to withdraw the approval of an NADA, the sponsor has the burden of proof to demonstrate that the product is safe and therefore that the NADA approval should remain in effect (21 CFR 12.87(d): (“At a hearing involving issuing, amending, or revoking a regulation or order relating to the safety or effectiveness of a drug . . . the participant who is contending that the product is safe or effective or both and who is . . . contesting withdrawal of approval has the burden of proof in establishing safety or effectiveness or both and thus the right to approval.”); (*see also Rhone-Poulenc, Inc. v. FDA*, 636 F.2d 750, 752 (D.C. Cir. 1980); *Hess & Clark v. FDA*, 495 F.2d 975, 992 (D.C. Cir. 1974)). Nevertheless, CVM bears an initial burden of showing that new evidence regarding the new animal drug raises serious questions about the safety of the new animal drug. *See Rhone-Poulenc*, 636 F.2d at 752. Once CVM has satisfied the initial burden, the burden shifts to the sponsor to establish the safety of the drug:

In the *Hess & Clark* case we held that the “new evidence” requirement of the safety clause “plainly places on the [CVM] an initial burden to adduce the ‘new evidence’ and what that evidence ‘shows’ . . . Only when the [CVM] has met this initial burden of coming forward with the new evidence is there a burden on the manufacturer to show that the drug is safe.” *Rhone-Poulenc*, 636 F.2d at 752 (quoting *Hess & Clark*, 495 F.2d at 992).

To meet its initial burden of proof to withdraw approval of a new animal drug that is “not shown to be safe,” CVM must provide “a reasonable basis from which serious questions about the ultimate safety of [the drug] and the residues that may result from its use may be inferred.” *See Diethylstilbestrol: Withdrawal of Approval of New Animal Drug Applications*; Commissioner’s Decision (44 FR 54852 at 54861,

September 21, 1979) (hereinafter DES Commissioner Decision) (quoting Proposal to Withdraw Approval of New Animal Drug Applications for Diethylstilbestrol, ALJ Initial Decision, Docket No. FDA-1976-N-0028 (formerly 76N-0002), I.D. at 8 (September 21, 1978)), *aff'd Rhone-Poulenc*, 636 F.2d 750; *see also* Nitrofurans Commissioner Decision (56 FR 41902 at 41902, August 23, 1991). Serious questions can be raised where the evidence is not conclusive but merely suggestive of an adverse effect. *See* DES Commissioner Decision.

### C. Withdrawal Under the Delaney Clause and the DES Proviso

Section 512(e)(1)(B) of the FD&C Act provides grounds for withdrawal of approval of an NADA if new evidence, tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available when the application was approved shows that the Delaney Clause, section 512(d)(1)(I) of the FD&C Act, applies to the drug. Under the Delaney Clause, the Secretary may not approve a new animal drug application if “such drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, induces cancer in man or animal” (section 512(d)(1)(I) of the FD&C Act). An exception to this general rule, referred to as the DES Proviso, allows for the approval of a carcinogenic new animal drug where FDA finds that, under the approved conditions of use: (1) The drug will not adversely affect the animals treated with the drug and (2) no residues of the drug will be found by an approved regulatory method in any edible tissues of or in any foods yielded by the animal (section 512(d)(1)(I)(i)-(ii) of the FD&C Act).

FDA has issued implementing regulations that set the requirements for demonstrating that no residues of the drug will be found by an approved regulatory method in any edible tissues of or in any foods yielded from the animal (21 CFR part 500, subpart E). These regulations, referred to as the sensitivity of the method regulations (SOM regulations), describe how FDA determines whether the regulatory method proposed by a sponsor to detect no residues of the carcinogenic drug is sufficiently sensitive to ensure that residues of carcinogenic concern in edible tissues will not exceed concentrations that represent no significant increase in the risk of cancer to humans.

Pursuant to these regulations, CVM determines for each drug and each drug

metabolite (on the basis of the results of chronic bioassays and other information) whether the drug or any of its metabolites should be regulated as a carcinogen (§ 500.84(a)). For the drug and each metabolite determined to be carcinogenic, CVM calculates, based upon submitted assays, the concentration of the test compound in the total diet of the test animal that corresponds to a maximum lifetime risk of cancer in the test animal of 1 in 1 million (§ 500.84(c)(1)). CVM designates the lowest value thus calculated as the  $S_o$  (§ 500.84(c)(1)). The  $S_o$  corresponds to a concentration of residue of carcinogenic concern in the total human diet that represents no significant increase in the risk of cancer to people (§ 500.82(b)). Residue of carcinogenic concern includes all compounds in the total residue of a demonstrated carcinogen excluding any compound judged by CVM not to present a carcinogenic risk (§ 500.82(b)). The total residues of carcinogenic concern (the drug and all of its metabolites less metabolites shown to be noncarcinogenic) are regulated based on the most potent carcinogenic residue (§ 500.84(c)(1)). This approach ensures that use of the drug does not present a significant increase in the risk of cancer when considering all residues in edible tissues.

Because the total diet is not derived only from food-producing animals, the SOM regulations make adjustments for human food intake of edible tissues, and determine the concentration of residues of carcinogenic concern in a specific edible tissue that corresponds to no significant increase in the risk of cancer to the human consumer. CVM assumes for purposes of these regulations that this value will correspond to the concentration of residues in a specific edible tissue that corresponds to a maximum lifetime risk of cancer in test animals of 1 in 1 million. This value is termed the  $S_m$  (§§ 500.82(b) and 500.84(c)(1)).

Based upon residue depletion data submitted by a sponsor, CVM selects a target tissue (the edible tissue selected to monitor for residues in the target animals) and a marker residue (a residue whose concentration is in a known relationship to the concentration of the residues of carcinogenic concern in the last tissue to deplete to the  $S_m$ ) and designates the concentration of the marker residue that the regulatory method must be capable of detecting in the target tissue (§ 500.86(a)-(c)). This value, termed the  $R_m$ , is the concentration of a marker residue in the target tissue when the residue of carcinogenic concern is equal to  $S_m$ ,

such that the absence of the marker residue in the target tissue above  $R_m$  can be taken as confirmation that the residue of carcinogenic concern does not exceed  $S_m$  in each of the edible tissues (§§ 500.82(b) and 500.86(c)). When the marker residue is at or below the  $R_m$ , the residue of carcinogenic concern in the diet of people does not exceed  $S_o$  (§ 500.86(c)).

A sponsor must submit a regulatory method that is able to detect the marker residue at or below the  $R_m$  (§§ 500.88(b) and 500.84(c)(2)) (“The LOD [Limit of Detection for the regulatory method] must be less than or equal to  $R_m$ .”). If a method cannot be developed that can detect the marker residue at or below the  $R_m$ , the requirements of the SOM regulations are not satisfied, and FDA cannot approve the drug. The DES Proviso and FDA’s implementing regulations are satisfied where no marker residue is detectable using the approved regulatory method under the proposed conditions of use of the drug, including the proposed preslaughter withdrawal period (§ 500.84(c)(3)).

As stated above, pursuant to section 512(e)(1)(B) of the FD&C Act, the Secretary shall, after due notice and an opportunity for a hearing, withdraw approval of an NADA if the Secretary finds that new evidence, tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available when the application was approved shows that the Delaney Clause applies to the drug. Evidence that the Delaney Clause applies to a drug exists where the drug has previously been determined to be a carcinogen and the new evidence shows CVM’s prior establishment of an analytical method and residue tolerance under the DES proviso exception to the Delaney Clause is inadequate. An analytical method is inadequate where new evidence demonstrates that the method does not accurately detect the marker residue or where new evidence demonstrates that not all residues of carcinogenic concern have depleted at the approved tolerance level of the marker residue (*see, e.g., Rhone-Poulenc*, 636 F.2d at 752-53.)

In establishing that grounds for withdrawal of approval exist under this clause, CVM carries an initial burden to demonstrate that the new animal drug and/or any of its metabolites induces cancer when ingested by man or animals. *Proposal to Withdraw New Animal Drug Applications for Furazolidone (NF-180) and Nitrofurazone (NF-7)*, ALJ Decision, FDA Docket No. FDA-1976-N-0511, at 73 (formerly 76N-0172; November 12,

1986) (hereinafter ALJ Decision, November 12, 1986). Once CVM has satisfied its initial burden, the sponsor bears the burden of showing that the drug satisfies the DES Proviso exception to the Delaney Clause and FDA's implementing regulations. ALJ Decision, November 12, 1986, at 73. ("Since furazolidone is also being challenged under the Delaney Clause, an additional issue . . . is whether new evidence put forth by the Center shows that furazolidone and/or its metabolites induces cancer when ingested by man or animal. If this burden is met, the sponsors must show [that the drug satisfies the DES proviso and FDA's implementing regulations]"); *see also* 21 CFR 500.92(b) (providing that for those compounds that FDA determines have been shown to induce cancer when ingested by man or animals, §§ 500.82 through 500.90 apply).

In this case, CVM had previously determined, in the approval and supplemental approvals of new animal drugs containing carbadox, that carbadox and its metabolites, including DCBX, induce cancer in animals, but that the drug could be approved under the DES Proviso exception to the Delaney Clause. *See* Section IV. However, new evidence raises questions about whether the drug is properly approved under the DES Proviso to the Delaney Clause and FDA's implementing regulations. *See* Criteria and Procedures for Evaluating Assays for Carcinogenic Residues (44 FR 17070 at 17104, March 20, 1979) (reproposal of rules revoked in accordance with court order). ("[The FD&C Act] defines the new evidence that the Commissioner can consider in determining whether a previously approved compound is safe. [Proper analytical methods establishing residue levels] are necessary to show that a sponsored compound is safe under the FD&C Act. For that reason, the absence of data satisfying the [criteria in 512(e)(1)(B) of the FD&C Act], in conjunction with the evidence already available about a compound, clearly can support the withdrawal of approval of an application."). In particular, new evidence indicating that an approved regulatory method can no longer be relied upon is sufficient to satisfy the Agency's burden to support withdrawal of approval under section 512(e)(1)(B) of the FD&C Act and the Delaney Clause:

In the case of an approved NADA for a carcinogenic compound, if FDA determines based on new information that the approved analytical method for detecting residues is inadequate . . . FDA could withdraw the approval on the basis of the Delaney Clause. Faced with evidence that an approved

method was inadequate, FDA could not make a finding that "no residue" of the sponsored compound would be found in the edible products of treated animals. The DES Proviso cannot begin to operate without that finding, and, accordingly, the Delaney Clause would preclude continued approval. *See* Sponsored Compounds in Food Producing Animals; Criteria and Procedures for Evaluating Safety of Carcinogenic Residues; Proposed Rule (50 FR 45530 at 45550, October 31, 1985); <sup>4</sup> *see* DES Commissioners' Decision (44 FR 54852 at 54859, September 21, 1979).

In this case, new evidence raises serious questions both about the acceptability of the current method in determining levels of known carcinogenic residues of carbadox, and, further, demonstrates that previously unidentified carcinogenic metabolites exist that are entirely unaccounted for in current approved testing methodology. Because the current analytic method is inadequate to identify the level of known carcinogens and does not identify the residue level of unidentified metabolites of carcinogenic concern, the current method and tolerance are inadequate to satisfy the DES Proviso.

#### *D. Withdrawal Under the General Safety Clause*

The General Safety Clause in section 512(e) of the FD&C Act provides grounds for withdrawal of approval of an NADA if new evidence, tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available when the application was approved shows that the drug is "not shown to be safe for use under the conditions of use upon the basis of which the application was approved" (section 512(e)(1)(B) of the FD&C Act). CVM has the initial burden to present new evidence that raises serious questions about the safety of the drug. Only upon that showing is there a burden on the manufacturer to demonstrate that the drug is safe. *See Rhone-Poulenc*, 636 F.2d at 752–53; *Hess & Clark*, 495 F.2d 975, 992 (D.C. Cir. 1974).

When evaluating a drug for withdrawal under the General Safety Clause, for CVM to satisfy its initial burden that new evidence raises serious human food safety questions, it must demonstrate a relationship between the

drug residues found in edible tissues and risk to human health.

[Without using] the Delaney Clause, it is not enough for the Commissioner merely to show that animal carcasses contain residues and that [the drug] is a carcinogen. Instead, the FDA must show that two different issues are resolved in its favor before it can shift to petitioners the burden of showing safety: (1) whether the detected residues are related to the use of [the drug]; (2) if so, whether the residues, because of their composition, and in the amounts present in the tissue, present some potential hazard to the public health. *See Hess & Clark*, 495 F.2d at 992 (D.C. Cir. 1974).

Applying this test, the D.C. Circuit Court of Appeals has held that new evidence of drug residues in edible tissues in conjunction with evidence that any drug residues of the drug in question present safety concerns is sufficient to satisfy CVM's burden of raising serious questions regarding the safety of the drug. *See Rhone-Poulenc*, 636 F.2d at 752–53. CVM, acknowledging the *Hess & Clark* standard and its subsequent application, has withdrawn approval of a new animal drug under the General Safety Clause where new evidence showed that: (1) The new animal drug was carcinogenic; (2) some drug metabolites were mutagenic; and (3) residues left in edible tissues at the withdrawal time were unidentified. *See* Nitrofurans Commissioners' Decision, 56 FR 41902 at 41910, August 23, 1991 ("Since the nature of these residues and their toxicity were not evaluated, they cannot be regarded as safe . . . Contrary to the sponsors' assertions, the evidence fails to demonstrate that furazolidone's metabolites pose no health risk to the human consumers. Given all the other evidence in the record demonstrating that furazolidone is a carcinogen and that its metabolites are mutagens, I find that, contrary to the sponsors' assertions, the metabolites of furazolidone pose a potential health risk to human consumers.") *see also* DES Commissioners' Decision, 44 FR 54852 at 54868 (explaining that, "[w]here new evidence shows that use of the drug results in residues of unidentified substances," CVM must decide whether, despite this lack of knowledge, "the drug may be considered to be 'shown to be safe[.]' " as the General Safety Clause requires). In other words, because residues of a mutagenic carcinogen are presumptively carcinogenic, and therefore presumptively unsafe, where new evidence demonstrates that unidentified residues of a mutagenic carcinogen remain at the time of withdrawal, the drug meets the standard set forth in *Hess & Clark*.

<sup>4</sup> Under FDA's regulations implementing the Delaney Clause for animal drugs, part 500, subpart E, a carcinogenic drug may not be approved if the regulatory method to test for the compound is not sufficiently sensitive. §§ 500.84(c)(2) and 500.88(b). A carcinogenic drug will be withdrawn if new evidence shows that an approved regulatory method is not sufficiently sensitive.

Applying the *Hess & Clark* standard here, the new evidence regarding carbadox clearly meets both prongs of that test. New evidence demonstrates that previously unidentified mutagenic residues of carbadox, a known carcinogen, remain present well after the established withdrawal period. As discussed further in Section V.D., because carbadox is a mutagenic carcinogen and QCA is the only known quantified noncarcinogenic residue of carbadox, all other residues are of carcinogenic concern. The new evidence demonstrates that the total residues of carcinogenic concern at the established 42-day withdrawal period are much higher than previously thought because the residues are no longer shown to be residues related to a noncarcinogenic compound, QCA, as previously believed. *See, infra*, Section V.D. Thus, the new evidence demonstrates that: (1) The unidentified residues are related to the use of carbadox and (2) the residues pose a potential hazard to public health because of the amount present and because they are residues of carcinogenic concern.

#### IV. Regulation of Residues of Carbadox

##### A. 1972 and 1975 Approvals

Carbadox is a carcinogen and was approved as a new animal drug pursuant to the DES Proviso exception to the Delaney Clause. At the time of the initial approval of carbadox in 1972, CVM (then the Bureau of Veterinary Medicine) recognized that carbadox is a carcinogen and therefore required that no residues of carbadox or its metabolite QCA be found in uncooked edible tissues of swine at the time of slaughter, as determined by the approved method of analysis. *See* 37 FR 20683, October 3, 1972, as amended by 37 FR 23906, November 10, 1972. This approval occurred prior to FDA's 1987 initial issue of regulations implementing the DES Proviso and therefore did not involve the development of a regulatory method sensitive enough to detect a marker residue that corresponded to a lifetime risk of cancer to test animals of 1 in 1 million (as described in Section III.C).

In this initial approval, based upon the submission of studies showing the depletion of carbadox residues in edible tissues, CVM determined that “[a]ll tissues except the liver [were] free of all residues” of unchanged carbadox at 24 hours after withdrawal of treatment and that unchanged carbadox “ha[d] disappeared from the liver after 24 hours” (Ref. 8). CVM also determined from submitted studies that the

carcinogenic parent drug was undetectable in liver at 24 hours (Id.). CVM further determined that a “restriction of use in the labeling provides a withdrawal period long enough [70 days] to assure no hazard to humans consuming residues in meat. In proper use there would be virtually no residues” of carbadox in tissues at slaughter (Ref. 9). The conclusions CVM made in 1972 regarding the rapid depletion of carcinogenic residues were later independently corroborated by a 1990 evaluation of carbadox by JECFA (Ref. 10 at p. 30).

Labeled use restrictions, as the drug was approved in 1972, included an upper weight limit of 75 pounds body weight and a prohibition on mixing into complete feeds containing less than 15 percent crude protein, thus limiting the drug's use to young pigs. These use restrictions provided assurances that the 70-day withdrawal period would likely be followed in practice (Ref. 11).

Similarly in 1975, FDA approved NADA 092–955 for the use of carbadox with pyrantel tartrate in Type C medicated swine feed (40 FR 45164, October 1, 1975). At that time, CVM reviewed drug residue studies of carbadox and pyrantel tartrate used in combination. The studies showed that, at 45 and 60 days withdrawal, concentrations of residues of carbadox in all tissues tested were undetectable using the previously approved analytical method with a 30 ppb limit of detection (Ref. 12 at p. 2).

##### B. 1986 Citizen Petition

On May 9, 1986, the Center for Science in the Public Interest submitted a citizen petition requesting that FDA withdraw approval of new animal drug applications for ipronidazole, dimetridazole, and carbadox (Ref. 13). The petition asserted that FDA must withdraw the approval of carbadox because carbadox and its metabolites DCBX and hydrazine were found to be carcinogenic, and the approved test method for carbadox residues is “unsuitable” (Ref. 13 at p. 20). The asserted unsuitability of the approved test method was based upon the fact that only a small portion of total residues had been positively identified and that the analytical method for carbadox residues was not sensitive enough to ensure that all residues had depleted.

FDA responded to the 1986 citizen petition in 1995 after a review of new residue depletion data submitted by (the then sponsor) Pfizer as well as data previously submitted to the Agency as part of the carbadox NADAs. Based upon this review, FDA denied the

petition as it related to carbadox because it determined that “if used according to label directions, residues of carbadox remaining in edible tissues of swine do not pose a human food safety risk to consumers” (Ref. 14 at p. 2). FDA based this safety determination on the following findings:

1. At 70 days withdrawal, the drug-related residue in swine liver measured 13 ppb.
2. Ten percent of the drug-related residue was extractable and identified to be a noncarcinogenic metabolite, quinoxaline-2-carboxylic acid.
3. The remaining 90% of the drug-related residue was unextractable or bound residues.
4. The bound residues were related to quinoxaline-2-carboxaldehyde and quinoxaline-2-carboxylic acid, both of which are of no carcinogenic concern. (Ref. 14 at p. 1).

##### C. Approval of 1998 Supplemental NADAs

In 1998, FDA approved two supplemental applications to NADA 041–061. The first supplement, approved in January 1998, assigned the noncarcinogenic metabolite QCA as the marker residue and set a tolerance of 30 ppb QCA in swine liver (Ref. 1).

Toxicology studies, including carcinogenicity bioassays with carbadox, DCBX (a primary metabolite of carbadox), and hydrazine were submitted as part of that supplemental application (Ref. 1 at pp. 1–5). The studies demonstrated the carcinogenicity of carbadox, DCBX, and hydrazine, and indicated that DCBX was the most potent of the three carcinogenic compounds (id.). Consequently, based on DCBX, CVM calculated an  $S_o$  of 0.061 ppb for total residues of carcinogenic concern for carbadox in the total diet (Ref. 1 at p. 5). CVM calculated an  $S_m$  value for total residues of carcinogenic concern in muscle at 0.305 ppb, in liver at 0.915 ppb, and in kidney and fat at 1.830 ppb (Ref. 1 at pp. 8–9).

The SOM regulations, as they existed in 1998, directed CVM to establish an  $R_m$  for carcinogenic compounds used in food-producing animals. CVM did not establish an  $R_m$  because CVM concluded the parent carbadox was rapidly metabolized, carcinogenic residues were not detectable beyond 72 hours post dosing, and unextracted residues<sup>5</sup> were

<sup>5</sup> Unextracted residues are residues of the drug that are not released when tissues are exposed to mild aqueous or organic extraction conditions. Guidance on analysis of unextracted total radiolabeled residue is provided in “Guidance for Industry: General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals (GFI #3),” 2006. Unextracted or bound residues can be either: (1) Endogenous components resulting from fragments of the radiolabeled

related to noncarcinogenic QCA and not of carcinogenic concern. Because the noncarcinogen QCA was the only detectable metabolite persisting beyond 72 hours post dosing, CVM assigned it as the marker residue (id.).

At the time it approved the supplement in January 1998, CVM said:

The sponsor and academic researchers have conducted numerous studies evaluating the fate of carbadox in animals. These residue depletion data are summarized in FAO Food and Nutrition Paper 41/3 (Food and Agriculture Organization (FAO) of the United Nations, 1991) and show that carbadox, desoxycarbadox and hydrazine do not persist in edible tissue as detectable residues beyond 72 hours. The agency's evaluation of these data, and the new information provided by the sponsor, demonstrate that following administration, parent carbadox is rapidly metabolized; that the metabolism of carbadox is similar among species; that the *in vivo* metabolism of the compounds of carcinogenic concern is also rapid and irreversible such that the resulting metabolic products cannot regenerate compounds of carcinogenic concern; that the unextractable residues are related to noncarcinogenic compounds, quinoxaline-2-carboxylic acid [QCA] and quinoxaline-2-carboxaldehyde; and that quinoxaline-2-carboxylic acid [QCA] is the only residue detectable in the edible tissues beyond 72 hours post dosing. Thus, the agency concludes that the unextractable bound residue is not of carcinogenic concern and that QCA is a reliable marker residue for carbadox. (Ref. 1 at p. 9).

CVM established a tolerance of 30 ppb for residues of QCA in liver, the tissue in which residues persist for the longest time. CVM concluded that the concentration of residues of carcinogenic concern in edible tissues was below the  $S_m$  when the

compound being incorporated into naturally occurring molecules such as amino or nucleic acids or (2) covalently bound residues. Covalently bound residues are considered to be of toxicological concern and their availability for absorption into the human gastrointestinal tract is considered during an evaluation of human food safety. Residues incorporated into endogenous molecules are not considered bioavailable or to be of toxicological concern. However, CVM has determined that establishing a potentially carcinogenic compound is bound and not of carcinogenic concern can be complicated by the possibility of gastrointestinal binding and gastrointestinal carcinogenesis and consequently can involve a more comprehensive assessment of the bound compounds as described in GFI #3. Note that while CVM has recognized that carbadox residues have not been fully extracted and characterized, CVM has not made an assessment that the compounds are not carcinogenic because they are bound to endogenous molecules (Ref. 15 at pp. 3–4). Moreover, residue studies presented to JECFA in 2003 suggest that carcinogenic residues that had not been extracted when exposed to organic extraction were released by simulated digestive enzymes (Ref. 2 at pp. 7–8, Table 5).

concentration of QCA in liver had depleted to 30 ppb.<sup>6</sup>

Under FDA's operational definition of "no residue," a residue of carcinogenic concern, so long as it does not exceed the  $S_o$ , may be detectable by an approved method. The residue data show that carbadox, desoxycarbadox and hydrazine do not persist in edible tissue as detectable residues beyond 72 hours. The *in vivo* metabolism of the compounds of carcinogenic concern is irreversible. Therefore, in this case, no residue of carcinogenic concern, even below the  $S_o$ , is detectable by any method. The unextracted residues are related to a noncarcinogenic compound, quinoxaline-2-carboxylic acid (QCA), and extractable QCA is the only residue detectable in the edible tissues 72 hours postdosing. Thus, the agency concludes that QCA is a reliable marker residue for carbadox and its metabolites.

From these data, FDA has selected liver as the target tissue and quinoxaline-2-carboxylic acid (QCA) as the marker residue. FDA has determined that when QCA, the marker, is at or below 30 ppb in the target tissue, liver, that no residue of carcinogenic concern, above the  $S_o$ , is detectable in each of the edible tissues by any method.

The sponsor has submitted a regulatory method capable of measuring QCA at and below 30 ppb in the target tissue. (Ref. 1 at p. 14).

As part of their application supporting the January 1998 supplemental approval, the sponsor submitted a regulatory method for residues of QCA in swine liver. The regulatory method relies on a gas chromatograph assay with electron capture detection and has a limit of quantification of 5 ppb (Ref. 1 at p. 13), a 6-fold improvement of the sensitivity from the previously approved regulatory method (Ref. 1.)

In October 1998, FDA approved an additional supplement to NADA 041–061 changing the withdrawal period for carbadox medicated feeds from 70 days to 42 days. The supplement was approved based upon the previous approval of a tolerance of 30 ppb for QCA and a residue depletion study that showed that residues of QCA in liver depleted below 30 ppb by 42 days (Ref. 16).

To summarize, in 1998, when FDA approved supplements to NADA 041–061 establishing a drug tolerance and shortening the withdrawal period, the evidence before CVM indicated:

- A 0.915 ppb concentration of total residues of carcinogenic concern in liver is the concentration that represents no significant increase in the risk of cancer

<sup>6</sup> The SOM regulations, as they existed in 1998, permitted approval of a regulatory method that could detect the marker residue of the drug, as long as the marker residue would only be detected at or below the  $R_m$  under the proposed conditions of use. See § 500.86(c) (1998).

to people—total residues of carcinogenic concern in liver above 0.915 ppb under the drug's approved conditions of use are unsafe. Such residues would preclude continued approval because the drug would not be shown to be safe and because the exception to the Delaney Clause would not apply (Ref. 1 at pp. 8–9, 10, 14).

- The parent compound carbadox is rapidly metabolized and carcinogenic residues of the drug are not identifiable in any edible tissues beyond 72 hours post dosing (Ref. 1 at p. 9).
- Remaining unextracted residues of carbadox are noncarcinogenic residues related to the noncarcinogenic metabolite QCA (Ref. 1 at pp. 9, 14).

- QCA is a reliable marker residue for carbadox and its metabolites; that is, measuring QCA residues in swine liver is a valid method for demonstrating the absence of residues of carcinogenic concern in edible tissues (id.).

Based upon these conclusions, CVM found that under the conditions of use the drug did not result in unsafe residues of carcinogenic concern in edible tissues and that the use of carbadox, as approved in the NADA supplements, satisfied the DES Proviso exception to the Delaney Clause prohibition on carcinogenic animal drugs (id.).

#### D. Approval of the 2004 Feed Use Combination

In 2004, FDA approved a combination drug medicated feed containing carbadox and oxytetracycline under NADA 141–211 (Ref. 17). In accordance with section 512(d)(4)(A) of the FD&C Act, approval of a combination new animal drug, where the underlying new animal drugs have previously been separately approved for particular uses and conditions of use for which they are intended for use in the combination, will not be refused on human food safety grounds unless the application fails to establish that: (1) None of the animal drugs used in combination, at the longest withdrawal period for any of the drugs in the combination, exceeds its established tolerance or (2) none of the drugs in the combination interferes with the method of analysis for any of the other drugs in the combination (section 512(d)(4)(A)(i)–(ii) of the FD&C Act). In other words, in order to approve a combination new animal drug for a drug product that contains two previously approved new animal drugs, no new information needs to be supplied to establish the safety of either drug. Instead, the application need only demonstrate that use of the drugs in combination will not result in violative

residues of any component drug or in drug assay interference.

Both carbadox and oxytetracycline had been previously and separately approved by FDA for the same conditions of use proposed for their use in combination. *See* 21 CFR 558.450 (Oxytetracycline); § 558.115 (Carbadox). The sponsor, Phibro, provided tissue residue depletion data demonstrating that QCA residues did not exceed the tolerance of 30 ppb when carbadox was administered in conjunction with oxytetracycline to swine (Ref. 17). A pharmacokinetic study comparing blood levels of oxytetracycline when administered alone and when administered in conjunction with carbadox satisfied the need to demonstrate that residues of oxytetracycline would not exceed the oxytetracycline tolerance at 42 days (*id.*).

The sponsor further provided data demonstrating noninterference of oxytetracycline with the method of analysis of QCA in liver (*id.*). Having made the required human food safety demonstrations for combination animal drugs, there was no basis to refuse approval of the product on human food safety grounds. The combination new animal drug was subsequently approved (*id.*).

#### V. New Information Regarding Carcinogenic Residues in Edible Tissues

Three sources provide new information regarding carcinogenic residues in edible tissues: Data submitted to the 2003 JECFA and the subsequent JECFA report (Ref. 2) and two publications in the peer-reviewed literature (Refs. 4 and 6).

JECFA is an internationally recognized expert body, providing the scientific evaluations that become the basis for international food standards established by the Codex Alimentarius Commission and supporting international treaties such as the Sanitary Phytosanitary Agreement. JECFA experts are chosen based on expertise, reputation, assurance of lack of conflict of interest, and familiarity with the subject of that particular evaluation.

In addition, pursuant to section 512(I)(1) of the FD&C Act,<sup>7</sup> FDA ordered Phibro to provide it with the same data provided to the 2003 JECFA. CVM evaluated the submitted data and found

that it raised questions regarding the safety of food resulting from swine treated with carbadox. Confidence in the information evaluated by the 2003 JECFA that is the basis for CVM's concern about carbadox was increased by the independent findings reported in the two publications discussed further.

#### A. New Information Provided to JECFA

In 2003, at the request of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), JECFA reevaluated the recommended Maximum Residue Limits (MRLs) for carbadox that were based upon a 1990 JECFA evaluation of the new animal drug (Ref. 2). CCRVDF, which includes CVM as a participant, determines priorities for the consideration of residues of veterinary drugs in foods and recommends MRLs for veterinary drugs to the Codex Alimentarius Commission of the Food and Agriculture Organization and the World Health Organization of the United Nations. The Codex Alimentarius Commission develops harmonized international food standards, guidelines, and codes of practice to protect the health of the consumers and ensure fair practices in food trade (see footnote 2).

Based on studies submitted to JECFA that showed the persistence of genotoxic, carcinogenic residues, JECFA could not determine an amount of residues of carbadox in human food that would have no adverse health effects in consumers. JECFA recommended that the Codex MRLs be withdrawn. CCRVDF concurred with JECFA's recommendation and proposed to the Commission that the MRLs be withdrawn. The Commission subsequently agreed and withdrew the Codex MRLs for carbadox (Ref. 18 at p. 120).

As part of the JECFA reevaluation process, Phibro presented two new residue studies to JECFA in 2003. Only one of these studies involved measurement of the depletion of carcinogenic metabolites of carbadox in edible tissues. In that study, animals were fed for 14 days at the approved dose of 55 ppm carbadox in feed (Ref. 2 at pp. 6–10). Animals were euthanized at various time points between 0 hours and 15 days post treatment, and samples of swine muscle, liver, skin, and fat were collected (Ref. 2 at pp. 7–8, Table 5).

Prior to analysis for residues, some of the tissue samples were exposed to human digestive enzymes<sup>8</sup> (Ref. 2 at p.

7). This *in vitro* model of bioavailability was designed to mimic effects of gastric fluid and intestinal fluid incubation in human stomach and small intestine to evaluate whether residues potentially could be released in the human gastrointestinal tract. To allow comparison, some tissue samples were left untreated while other tissue samples were incubated in simulated gastric fluid (with pepsin) or in simulated intestinal fluid (with pancreatin). Residues of carbadox, DCBX, and QCA were measured in the untreated tissues, in tissues that were incubated with enzymes, and in the supernatant of those tissues that were incubated with enzymes (*id.*).

Residues of carbadox, DCBX, and QCA were measured by liquid chromatography-atmospheric pressure chemical ionization tandem mass spectrometry (LC/APCI-MS/MS). The tissue samples that were not incubated with enzymes were extracted with acetonitrile prior to analysis. The tissue samples that were incubated with enzymes were extracted with ethyl acetate prior to analysis. Supernatants of the enzyme digestion were analyzed directly without extraction. The limits of quantification for LC/APCI-MS/MS were 0.050 ppb for carbadox residues and 0.030 ppb for DCBX residues (*id.*). The detection capabilities of this methodology were greatly enhanced compared to the previous method for carbadox and DCBX (*i.e.*, the method used for the previous analytical work had a detection limit of 2 ppb) (Ref. 20).

The study presented to JECFA showed that residue concentrations of carbadox and DCBX were higher and persisted for a longer period post dosing in liver than in the other sampled tissues. In liver without treatment with simulated digestive fluids, carbadox was detectable (0.050 ppb) as long as 48 hours post dosing and DCBX was detectable (0.138 ppb) at the last sampling time point, which was 15 days post treatment (Ref. 2 at pp. 7–8, Table 5). Treatment of tissues with simulated digestive fluids resulted in measurement of significantly higher concentrations of DCBX. "Pretreatment of the samples with digestive fluids increased the amounts of carcinogenic residues found in all tissues. In liver the concentration of . . . [DCBX] increased by more than fourfold when the samples were treated with intestinal fluid, and large quantities were present 15 days after withdrawal . . ." (Ref. 2 at p. 17).

"Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Metabolism Study to Determine the Quantity and Identify the Nature of Residues (MRK)," Sept. 15, 2011 (Ref. 19).

<sup>7</sup> An order issued pursuant to section 512(I) of the FD&C Act, requires a sponsor to submit such data and information as FDA may find necessary to determine or facilitate a determination whether grounds to withdraw approval of an NADA under section 512(e) of the FD&C Act exist.

<sup>8</sup> The use of enzymic preparations to characterize residues is described in section 2.3.4.3.2 of CVM Guidance for Industry (GFI) #205 VICH GL 46,

In particular, the study showed that concentrations of approximately 35 ppb of DCBX at 0 hours post dosing and approximately 2.7 ppb of DCBX at 15 days post dosing were measured in liver treated with pancreatin (Ref. 2 at p. 8, Table 5). The significantly increased residues found in liver after treatment with intestinal enzymes show that enzymatic treatment was able to release carcinogenic residues that were not extractable by organic solvents, such as those used in tissue residue studies to support the original and supplemental approval of NADAs for use of carbadox.

JECFA evaluated the percent recoveries of the analytes. Percent recovery is a measurement of accuracy of the analytical procedure and expresses the closeness of agreement between the true value of the analyte concentration and the mean value obtained by applying the analytical procedure (Ref. 21). JECFA reported that when carbadox, DCBX, and QCA were incubated for 4 hours with digestive enzymes, carbadox and DCBX were unstable (percent recovery decreased) in the samples treated with pepsin, but were stable in pancreatin (Ref. 2 at p. 16). JECFA also reported that the recoveries of the analytes from the liver samples were generally variable and decreased to low levels when digestive enzymes were used prior to extraction (Ref. 2 at pp. 17–18).

After evaluating the residue study, JECFA concluded that the poor recoveries obtained with the enzyme experiments “showed that the true concentrations of the carcinogenic metabolites in tissues cannot yet be estimated with certainty, since an unknown portion of the releasable residue [of carbadox and DCBX] is destroyed during incubation [of liver tissues] with the [digestive] enzymes” (Ref. 2 at p. 18). JECFA therefore concluded that the measured values of DCBX and carbadox “represent[ed] a lower estimate of the total present in the tissue” (id.).

Presented with data demonstrating both the depletion of QCA and depletion of the carcinogenic residue DCBX, JECFA established a relationship between the concentrations of QCA and DCBX in liver (Ref. 2 at p. 14). The statistical analysis of the data showed a linear relationship between the logarithms of the concentrations of QCA and DCBX (Ref. 2 at pp. 14, 18). This relationship allowed JECFA to use regression analysis to assess the concentrations of DCBX when QCA depleted to 30 ppb in liver (the Codex MRL and FDA approved tolerance for carbadox). JECFA determined that “[a]t the MRL [of 30 ppb] for QCA in liver,

the average concentrations of the carcinogenic residue desoxy-carbadox in liver estimated by regression analysis were about 4 [ppb]” (Ref. 2 at pp. 14, 16–17). JECFA recognized that “tolerance limits for the concentration of desoxycarbadox were several times higher owing to the wide variation of the data” and thereby concluded that “QCA is not a suitable marker for monitoring carcinogenic metabolites of carbadox in liver . . . and QCA does not ensure the absence of carcinogenic residues” (Ref. 2 at p. 17).

In contrast to the previous findings of JECFA, these new data show that carcinogenic residues, in particular DCBX, are present in edible tissues for a significant time during the depletion of parent carbadox (Ref. 2 at p. 18). Moreover, the study shows that treatment with simulated digestive enzymes releases higher levels of the carcinogenic residues DCBX than were recovered using organic extractions in the study. These higher concentrations provide evidence that the carbadox residues that were not extractable or identified in previous studies submitted to the Agency could include carcinogenic residues of carbadox that are releasable with enzymatic treatment of tissues. This evidence calls into question the Agency’s previous conclusions that all unextracted and unidentified residues were noncarcinogenic residues related to QCA.

After reviewing the new residue data, and considering the previously evaluated genotoxicity and carcinogenicity data, JECFA recommended withdrawal of the previously established Codex MRLs (Ref. 2 at p. 18). Codex subsequently agreed and withdrew the MRLs for carbadox (Ref. 18 at p. 120).

In summary, the studies considered by JECFA during its 2003 review of the drug indicated that:

- Residues of the carcinogenic metabolite of carbadox, DCBX, were measured in edible tissues for 15 days, which was the last sampling time point. DCBX was measured in swine liver after treatment with simulated digestive enzymes at concentrations as high as 2.69 ppb at 15 days post treatment (Ref. 2 at p. 8, Table 5).

- Analysis of measured concentrations of QCA and DCBX in liver indicated that approximately 4 ppb of DCBX would be present in the liver of treated animals when QCA reached the Codex MRL and the FDA tolerance of 30 ppb in liver (Ref. 2 at pp. 14, 17). This concentration of DCBX alone is more than 4 times higher than the concentration of total residues of

carcinogenic concern in liver that would present no significant increase in the risk of cancer to people.

- Residues of carbadox previously unextracted from edible tissues could be released by gastric and intestinal fluids that mimic the human digestive process (Ref. 2 at p. 16). The enzymatic treatment used in the study significantly increased the recoveries of concentrations of DCBX and carbadox from edible tissues, thereby indicating that some portion of the previously unextracted and unidentified total residues is composed of carcinogenic compounds.

#### *B. Additional New Evidence*

Following the reports of the 2003 JECFA reevaluation of carbadox, CVM requested that Phibro also provide the carcinogenic residue depletion study to CVM. In 2005, in response to CVM’s request for information, Phibro submitted a summary of the carcinogenic residue depletion study previously provided to JECFA. Upon review of the summary data, CVM asked Phibro to submit existing studies or provide new and complete studies that address the relationship of QCA at 30 ppb and carbadox and DCBX residues, and about the use of QCA as the marker residue for surveillance purposes. In 2006, CVM asked for and received from Phibro a timeline for submission of complete information that addresses concerns about the relationship of QCA at 30 ppb and carbadox and DCBX residues, and about the use of QCA as the marker residue for surveillance purposes. Between 2006 and 2011, interactions between CVM and Phibro continued, with protocols submitted and reviewed, method validation reports submitted and reviewed, informal communications by email, and informal discussions by telephone. The focus of the interactions was development and validation of methods to measure QCA and DCBX in a tissue residue depletion study. Despite the continued interaction between Phibro and CVM, Phibro has not submitted the requested information.

In 2011, pursuant to section 512(J)(1) of the FD&C Act, FDA ordered Phibro to provide all information in its possession with respect to: (1) The persistence of DCBX in edible tissues; (2) the appropriateness of QCA as an analyte for residue monitoring and for establishing a withdrawal time for the use of carbadox in pigs; and (3) whether an analytical method for monitoring carbadox-related carcinogenic residues in edible tissues can be developed that would comply with part 500, subpart E.

In response to the 2011 FDA order, Phibro provided CVM with the full study report and appendices, previously provided to JECFA in 2003.

CVM has independently evaluated the data from the Phibro study of depletion of carcinogenic residues reviewed by JECFA in 2003, and in particular has reviewed the JECFA conclusion that when QCA reaches 30 ppb in liver, residues of DCBX in liver are “estimated by regression analysis to be about 4 [ppb]” (Ref. 2 at p. 18). CVM’s statistical analysis of the residue concentrations of DCBX in liver treated with pancreatin (a simulated intestinal fluid) shows that concentrations of DCBX in liver, when QCA reaches the 30 ppb approved tolerance, would average 4 ppb and, based on the data in the JECFA report, could reasonably range from 1.4 ppb to 11 ppb, using a 95 percent prediction range. Based upon this analysis, DCBX alone—leaving aside additional, unidentified residues of carcinogenic concern—significantly exceeds the approved  $S_m$  when QCA, the approved marker residue, reaches the approved tolerance. The new evidence from the 2003 JECFA re-evaluation of carbadox, along with studies that were later submitted to CVM, undermine the human food safety conclusions that CVM had previously reached when considering the approval of the new animal drug applications for carbadox for its various uses. CVM has engaged with Phibro to evaluate the carbadox-associated safety concerns raised by the new evidence and repeatedly has asked Phibro to submit information that would address these safety concerns. Information provided by Phibro in response to these requests has not resolved CVM’s human food safety concerns.

#### 1. Boison, et al., 2009

In addition, a 2009 publication calls into question conclusions made by CVM when it approved the NADAs and supplemental NADAs for carbadox (Ref. 4). Boison, *et al.*, 2009, demonstrates the availability of a sensitive analytical method for DCBX, and provides information from which serious questions about the safety of carbadox can be inferred, specifically whether DCBX may be present in edible tissues of treated swine above the  $S_m$  even when the marker residue (QCA) concentration is below the tolerance of 30 ppb (*id.*).

Boison, *et al.*, report: (1) QCA is not a suitable marker for the regulation of carbadox because while QCA is very stable under temperature conditions above 60 °C (*i.e.*, 105 °C), DCBX is not (Ref. 4 at p. 133); (2) the existence of an

analytical method capable of detecting DCBX below the  $S_m$  for porcine muscle and liver (Ref. 4 at p. 132, Table 5); and (3) detection of DCBX at a concentration greater than 0.050 ppb in the diaphragm (but not the liver) of 2 of 6 hogs fed carbadox, while QCA was not detected in the liver of those same hogs at a limit of quantitation (LOQ) of 0.500 ppb (Ref. 4 at pp. 132–33). The findings of Boison, *et al.*, are significant for two reasons: (1) QCA appears not to be a reliable marker residue and (2) DCBX is reported to be sensitive to the processing temperature used in the analytical method.

#### 2. Baars, et al., 1991

In 2012, in response to FDA’s 2011 order under section 512(I) of the FD&C Act, Phibro sent CVM a letter citing Baars, *et al.*, 1990 (Ref. 5), an abstract of a study not previously provided. CVM obtained the study report Baars, *et al.*, 1991 (Ref. 6), which reports an analytical method with a limit of detection of 1 ppb that detects the presence of DCBX in edible tissues for greater than 72 hours after removal of feed containing carbadox. Specifically, Baars, *et al.*, 1991, demonstrated the presence of DCBX for up to 7 days (~168 hours) in the kidney and 14 days (~336 hours) in the liver of swine fed carbadox (Ref. 5 at p. 3, Fig. 3; Ref. 6 at p. 290, Fig. 2). This observation called into question CVM’s previous conclusion that all residues of carcinogenic concern deplete within 72 hours.

#### C. New Evidence Calls Into Question Prior CVM Conclusions That Were the Basis of the 1998 Supplemental Approval

CVM’s prior conclusion that QCA is a reliable marker residue for carbadox and its metabolites was predicated on several underlying conclusions (Ref. 1 at pp. 13–14). These underlying conclusions are reviewed below in light of the new evidence presented above.

1. Previous Conclusion 1: The residue data show that carbadox, DCBX, and hydrazine do not persist in edible tissues as detectable residues beyond 72 hours.<sup>9</sup>

Since the time CVM made this previous conclusion, we have become aware of information that undermines the previous conclusion that carbadox and its carcinogenic metabolites do not persist in edible tissues beyond 72 hours. JECFA, in 2003, reviewed a study detecting DCBX in livers of swine up to 15 days after cessation of carbadox

exposure. The study JECFA reviewed was limited to 15 days. The data presented to JECFA in 2003 provide new scientific evidence that DCBX persists in edible tissues of swine as a detectable residue beyond 72 hours (Ref. 2).

Further, Baars, *et al.*, 1991, reports detecting DCBX in liver up to Day 14 after cessation of exposure to carbadox using an analytical method with a detection limit of 1 ppb (Ref. 6). Baars, *et al.*, 1991, provides new scientific evidence that DCBX persists as a detectable residue in edible tissues of swine for greater than 72 hours.

Scientific evidence from JECFA’s 2003 evaluation of submitted information and Baars, *et al.*, 1991, demonstrate that DCBX, one residue of carcinogenic concern for carbadox, persists in edible tissues of swine beyond 72 hours. All of this evidence was first received by CVM after the 1998 approval of the supplemental application to NADA 041–061. Based on this new scientific evidence, the previous conclusion that DCBX does not persist in edible tissues of swine as a detectable residue beyond 72 hours is no longer justified.

2. Previous Conclusion 2: The unextracted residues are related to a noncarcinogenic compound, QCA, and extractable QCA is the only residue detectable in the edible tissues of swine 72 hours post dosing.<sup>10</sup>

At the time of the 1998 supplemental approval, CVM concluded that that unextracted residues were related to the noncarcinogenic compound, QCA, and that extractable QCA was the only residue detectable in the edible tissues after 72 hours post dosing. However, CVM is now aware of reports of extraction of residues being enhanced by pepsin or pancreatin digestion prior to organic extraction, making non-QCA residues previously thought to be unextractable currently extractable (Ref. 2). JECFA reports that some residues of carbadox previously identified as unextractable can now be extracted (*id.*). DCBX was found in the newly extractable residues. This scientific evidence demonstrates that some residues previously found to be unextractable are extractable and that the unextractable residues are not all related to QCA.

As discussed above, residues of DCBX, a residue of carcinogenic concern, have been detected in edible tissues longer than 72 hours post dosing

<sup>9</sup>This underlying conclusion is described in the January 30, 1998, summary basis of approval under the Freedom of Information Act (FOI Summary) for NADA 041–061 (Ref. 1 at p. 9) and in the report of the 1990 JECFA meeting (Ref. 10 at p. 30).

<sup>10</sup>This underlying conclusion is described in the January 30, 1998, summary basis of approval under the Freedom of Information Act (FOI Summary) for NADA 041–061 (Ref. 1 at p. 9) and in the report of the 1990 JECFA meeting (Ref. 10 at p. 30).



(Refs. 2, 5, and 6). The previous underlying conclusions that unextracted residues are related to noncarcinogenic compound, QCA, and extractable QCA is the only residue detectable in the edible tissues 72 hours post dosing is no longer justified based on new scientific evidence.

3. Previous Conclusion 3: No residue of carcinogenic concern even below the  $S_0$ , is detectable by any method beyond 72 hours.<sup>11</sup>

Boison, et al., 2009, reports a method capable of detecting DCBX at 0.05 ppb, which is below the 0.061 ppb  $S_0$  and below the  $S_m$  of 0.305 ppb in muscle, 0.915 ppb in liver, and 1.83 ppb in kidney and fat. The method is also capable of measuring QCA at 0.500 ppb, below the current tolerance of 30 ppb (Ref. 4 at p. 132, Table 5). Consequently, measurement of the relationship of QCA to at least one residue of carcinogenic concern, DCBX, is now scientifically feasible at the time the last tissue depletes to its  $S_m$ . In fact, Boison, et al., 2009, reports the presence of DCBX at a concentration greater than 0.050 ppb in the diaphragm (muscle) of 2 of 6 market-weight hogs fed carbadox, when QCA was not detected, at a limit of quantitation of 0.50 ppb, in the livers of those same hogs (Ref. 4 at pp. 132–133). This evidence raises a serious question about whether QCA at 30 ppb is an appropriate marker residue for carbadox residues of carcinogenic concern. Based on this new scientific evidence, the previous underlying conclusion that no residue of carcinogenic concern, even below the  $S_0$ , is detectable by any method beyond 72 hours is no longer justified.

4. Previous Conclusion 4: QCA is a reliable marker residue for carbadox and its metabolites.<sup>12</sup>

In light of the new evidence presented above, the conclusion that QCA is a reliable marker residue for carbadox and its metabolites is no longer justified because: (1) Previous conclusions made by the Agency are no longer scientifically justified and (2) the

relationship of QCA to a carbadox residue of carcinogenic concern, DCBX, in the last tissue to deplete to its  $S_m$  is not known.

*D. CVM's Reanalysis of the Human Health Risk From Previously Submitted Residue Data*

CVM reevaluated the existing carbadox residue data as a result of discussions that took place during meetings in 2011 with Phibro about the composition of total residues of carbadox (Refs. 3 and 22). CVM also reexamined the residue data submitted in support of the 1998 NADA supplements in light of the new understanding from the 2003 JECFA report that carcinogenic residues of carbadox persisted in edible tissues for 15 days, which was the last sampling time point, and that the previously unextractable residues are not necessarily noncarcinogenic residues related to QCA (Ref. 2).

Using data in the FOI Summary for the January 30, 1998, supplemental approval, CVM reviewed information on total residue concentrations (measured from total radioactivity present in tissue from swine administered the radiolabeled drug), as well as the percent of total residues represented by QCA—the only noncarcinogenic metabolite of carbadox identified and quantified in the total residues of carbadox (Ref. 1). CVM used the total residue data and the percent of total residues represented by QCA to calculate the total residue of carcinogenic concern present in liver. Under the SOM regulations, “residues of carcinogenic concern” in edible tissues are total residues of a carcinogenic drug minus identified residues that are judged by CVM to be noncarcinogenic (§ 500.82(b)). CVM previously excluded the unextracted portions of total residues from carcinogenic concern because it believed they were noncarcinogenic, QCA-related residues. The data presented to JECFA in 2003 now refute

that conclusion, and CVM has no information, from Phibro or otherwise, that identifies or measures noncarcinogenic residues other than QCA in total residues of carbadox at the withdrawal period. As such, CVM now identifies the total residue of carcinogenic concern by subtracting QCA (identified residues that are confirmed to be noncarcinogenic) from total residues of carbadox. Determining the concentration of residues of carcinogenic concern present in the liver allowed CVM to compare that value with the  $S_m$  established for residues of carcinogenic concern in liver.

CVM reviewed data regarding concentrations of total residues in swine tissues following 5 days of feeding <sup>14</sup>C-carbadox contained in a residue depletion study (the same study submitted to JECFA for its 1990 evaluation of carbadox (Ref. 10 at p. 31)) submitted by the sponsor in support of the supplemental application to NADA 041–061 approved in January 1998 (Ref. 1, Study No. 1525N–60–87–005). The study measured concentrations of total residues of <sup>14</sup>C-carbadox and residues of QCA. Using these data, the study reported QCA as a mean percentage of the total residues of carbadox. QCA represented 24.4 percent of the total residues at 30 days, 27.5 percent at 45 days, and 9.9 percent at 70 days post dosing (Ref. 1 at p. 13, Table 9).

Table 1 presents total carbadox residues and total carbadox residues minus the noncarcinogenic QCA. Column 1 lists the sampling time point when swine were slaughtered following administration of the last dose of carbadox. Column 2 presents mean total residues measured in livers collected from swine slaughtered at each time point. Column 3 lists the mean QCA percentage of total residues at each time point. Column 4 lists the calculated mean total residues of carcinogenic concern based on a subtraction of QCA from the mean total residue values in Column 2.

TABLE 1—MEAN TOTAL RESIDUES MEASURED AS <sup>14</sup>C-CARBADOX EQUIVALENTS, THE MEAN PERCENTAGE OF TOTAL RESIDUES REPRESENTED BY QCA, AND MEAN TOTAL RESIDUE OF CARCINOGENIC CONCERN IN LIVER OF SWINE (N=3 OR 4) FOLLOWING 5 DAYS OF FEEDING <sup>14</sup>C-CARBADOX AT 55 PPM

Days post dosing	Total residues (ppb)	Percent QCA	Total residue of carcinogenic concern (ppb) <sup>1</sup>
30	74.5	24.4	56.3
45	20.0	27.5	14.5

<sup>11</sup> This underlying conclusion is part of the basis of the January 1998 supplemental approval (FOI Summary) (Ref. 1 at pp. 13–14).

<sup>12</sup> This underlying conclusion is part of the basis of the January 1998 supplemental approval (FOI Summary) (Ref. 1 at pp. 13–14).

TABLE 1—MEAN TOTAL RESIDUES MEASURED AS <sup>14</sup>C-CARBADOX EQUIVALENTS, THE MEAN PERCENTAGE OF TOTAL RESIDUES REPRESENTED BY QCA, AND MEAN TOTAL RESIDUE OF CARCINOGENIC CONCERN IN LIVER OF SWINE (N=3 OR 4) FOLLOWING 5 DAYS OF FEEDING <sup>14</sup>C-CARBADOX AT 55 PPM—Continued

Days post dosing	Total residues (ppb)	Percent QCA	Total residue of carcinogenic concern (ppb) <sup>1</sup>
70 .....	13.3	9.9	11.98

<sup>1</sup> Values calculated by subtracting noncarcinogenic QCA portion from total residues.

FDA first approved the use of carbadox in 1972 prior to the issuance of the Agency's SOM regulations. CVM did not make a calculation comparing total residues less QCA to the  $S_m$  in approving the January 1998 NADA supplement because the data available at the time indicated that DCBX was not detectable beyond 72 hours post dosing (by the analytical method used at the time) and because CVM believed all unextractable residues were noncarcinogenic residues related to QCA (Ref. 1). No residue depletion data presented to the Agency in original or supplemental NADAs showed that carcinogenic residues persisted beyond 72 hours or that the unextractable residues were carcinogenic. As a result, CVM did not, at that time, ask for data regarding the composition of total residues beyond establishing QCA as an appropriate marker residue. New evidence presented to JECFA in 2003 and reported by Boison, et al., 2009, and Baars, et al., 1991, calls CVM's prior conclusions into question and places new significance on the concentrations of total residues of carcinogenic concern for carbadox (Refs. 2, 4, and 6).

The individual data shown as mean values in Table 1 were used to predict total residues of carcinogenic concern at the approved 42-day withdrawal period for carbadox in NADAs 041–061 and 141–211, and the approved 70-day withdrawal period for carbadox in NADA 092–955. CVM analyzed the data using the logarithm of the dependent variable (carbadox-equivalents in liver). The logarithmic transformation or "exponential model" is consistent with the published JECFA analyses of carbadox and commonly observed elimination behavior of pharmaceuticals (Ref. 22). Using this modeling procedure, the total residues of carcinogenic concern at 42 days are estimated to be 27 ppb with a 95 percent prediction interval of 9 ppb to 80 ppb (Ref. 3 at p. 17, Table 8). These predictions can be compared with the  $S_m$  for swine liver of 0.915 ppb. The regression model predicts that swine liver concentrations of total carcinogenic residues will be

significantly in excess of the  $S_m$ —approximately 30-fold (27 ppb ÷ 0.915 ppb = 29.51) greater residues of carcinogenic concern than the  $S_m$  at the approved 42-day withdrawal period for NADAs 041–061 and 141–211 (Ref. 3 at p. 16). Total residues of carcinogenic concern at 70 days are estimated to be 10 ppb with a 95 percent prediction interval of 3 ppb to 32 ppb (Ref. 3 at p. 17, Table 8). The analysis predicts that swine liver concentrations of total carcinogenic residues will be significantly in excess of the  $S_m$ —approximately 11-fold greater residues of carcinogenic concern than the  $S_m$  at the approved 70-day withdrawal period for NADA 092–955.

Approval of a carcinogenic new animal drug under the DES Proviso to the Delaney Clause requires development of a sufficiently sensitive regulatory method that detects no residues of carcinogenic concern in the edible tissues of food-producing animals from the use of the animal drug. New evidence raises serious questions about whether the currently approved tolerance for uses of carbadox is adequate under the SOM regulations, and raises serious questions about the continued approval of the compound under the DES Proviso exception to the Delaney Clause due to the lack of a sufficiently sensitive regulatory method.

Carbadox is currently approved based upon CVM's previous conclusion that unextractable residues were QCA related and noncarcinogenic. Given this conclusion and the fact that no residues of carcinogenic compounds were detectable by any method beyond 72 hours, CVM determined that QCA was an acceptable marker residue and established the tolerance at 30 ppb. New evidence presented to JECFA in 2003 undermines the conclusion that all unextractable residues at the withdrawal period are QCA related. As a result, under FDA's SOM regulations, all unextractable residues except for measured residues of QCA must be considered residues of carcinogenic concern (§ 500.82(b)). Under CVM's analysis (Table 1), concentrations of total residues of carcinogenic concern in

liver are approximately 30 times higher than the  $S_m$  at the approved 42-day withdrawal period and 11 times higher at the approved 70-day withdrawal period (Ref. 3 at pp. 16–17). CVM would expect that total residues of carcinogenic concern would also exceed the  $S_m$  when QCA reaches the approved tolerance of 30 ppb in liver. CVM can no longer conclude that when QCA is at or below 30 ppb, the residues of carcinogenic concern are present at or below a concentration that would present no significant increase in the risk of cancer to humans (§ 500.86(c)).

The new evidence indicates that QCA is not an appropriate marker residue for residues of carcinogenic concern and that QCA at 30 ppb in swine liver is not an appropriate tolerance. The new evidence also shows that the approved regulatory method for all approved carbadox NADAs is inadequate under the SOM regulations (part 500, subpart E). The inadequacy of the regulatory method is a basis for withdrawal of approval of all carbadox NADAs under section 512(e)(1)(B) of the FD&C Act. See *Sponsored Compounds in Food-Producing Animals; Criteria and Procedures for Evaluating the Safety of Carcinogenic Residues, Proposed Rule*, preamble to the proposed SOM regulations II (50 FR 45530 at 45550).

Similarly, these findings demonstrate that carbadox is no longer shown to be safe under the General Safety Clause because residues of carcinogenic concern remain in swine tissue well past the established withdrawal period. Under the General Safety Clause, drug residues must be determined to be safe based on all available evidence. Where a drug is a known mutagenic carcinogen and new evidence shows that unidentified residues of carcinogenic concern are present at the established withdrawal time, the drug is no longer shown to be safe. See Section III.D.

As stated previously, the new evidence presented to JECFA undermines the previously held conclusion that all unextracted residues are QCA related and noncarcinogenic. Because carbadox is a mutagenic carcinogen, all otherwise unidentified

residues are treated as carcinogenic. No evidence has been presented to CVM by Phibro or any other source to show that the unidentified residues are noncarcinogenic or that the residues do not otherwise present a threat to public health. As a result, carbadox is not shown to be safe under the General Safety Clause.

#### VI. Notice of Opportunity for a Hearing

New evidence regarding carcinogenic residues in edible tissues of swine treated with carbadox raises serious questions about the human food safety of the drug. Therefore, CVM is proposing to withdraw approval of the three NADAs that provide for use of carbadox in swine feed because new evidence demonstrates that the drug no longer meets the DES Proviso exception to the Delaney Clause and because new evidence demonstrates that carbadox is not shown to be safe under the General Safety Clause.

Therefore, notice is given to Phibro Animal Health Corp., 65 Challenger Rd., Ridgefield Park, NJ 07660, and to all other interested persons, that the Director of CVM proposes to issue an order under section 512(e) of the FD&C Act withdrawing approval of all NADAs providing for use of carbadox in medicated swine feed.

In accordance with section 512 of the FD&C Act and part 514 (21 CFR part 514) and under the authority delegated to the Director of CVM, Phibro Animal Health Corp., the sponsor, is hereby given an opportunity for hearing to show why approval of NADAs 041–061, 092–955, and 141–211 should not be withdrawn.

If the sponsor, Phibro Animal Health Corp., wishes to request a hearing the sponsor must file: (1) On or before [see **DATES**], a written notice of appearance and request for a hearing and (2) on or before [see **DATES**], the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact to justify a hearing as specified in § 514.200. Any other interested person may also submit comments on this notice (see, **ADDRESSES**). Procedures and requirements governing this NOOH, a notice of appearance and request for a hearing, submission of data, information, and analyses to justify a hearing, other comments, and a grant of denial of a hearing, are contained in § 514.200 and 21 CFR part 12.

The failure of a holder of an approval to file timely a written appearance and request for hearing as required by § 514.200 constitutes an election not to avail himself or herself of the opportunity for a hearing and a waiver

of any contentions concerning the legal status of any such drug product, and the Director of CVM will summarily enter a final order withdrawing the approvals. Any new animal drug product marketed without an approved NADA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations of denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that there is no genuine and substantial issue of fact that precludes the withdrawal of approval of the applications, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person who requests a hearing, making findings and conclusions, and denying a hearing.

If a hearing is requested and is justified by the sponsor's response to this NOOH, the issues will be defined, a presiding officer will be assigned, and a written notice of the time and place at which the hearing will commence will be issued as soon as practicable.

This notice is issued under section 512 of the FD&C Act and under the authority delegated to the Director of CVM.

#### VII. Environmental Impact

The Agency has determined under 21 CFR 25.33(g) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### VIII. Paperwork Reduction Act of 1995

The collections of information requirements for this document are covered under OMB control numbers 0910–0032 and 0910–0184.

#### IX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA, Freedom of Information (FOI) Summary, NADA 041–061, MECADOX 10 (carbadox) Type A medicated article,

supplemental approval January 30, 1998. Available at <http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/UCM429999.pdf> (accessed on March 19, 2016).

2. JECFA, Report on Carbadox, 2003. Available at <ftp://ftp.fao.org/ag/agn/jecfa/vetdrug/41-15-carbadox.pdf> (accessed on March 19, 2016).
3. FDA, Memorandum to the File, Claycamp, H.G., “Preliminary Risk Characterization: Cancer Risk Estimation from Carbadox Residues in Pork from Swine Treated with Carbadox,” December 16, 2014.
4. Boison, J.O., S.C. Lee, and R.G. Gedir, “A Determinative and Confirmatory Method for Residues of the Metabolites of Carbadox and Olaquinox in Porcine Tissues,” *Analytica Chimica Acta*, 637:128–134, 2009.
5. Baars, A.J., L.A. van Ginkel, M.M.L. Aerts, et al., “Kinetics of Carbadox Residues in Pigs,” In: *Proceedings of the EuroResidue Conference, Noorwijkerhout* (Haagsma, N., A. Ruiter, and P.B. Czedik-Eysenberg, eds., May 21–23, 1990).
6. Baars, A.J., L.P. Jager, T.J. Spierenberg, et al., “Residues of Carbadox Metabolites in Edible Pork Products,” *Archives of Toxicology Supplement*, 14:288–92, 1991.
7. FDA, CVM Guidance for Industry (GFI) #3, “General Principles for Evaluating the Safety of Compounds Used in Food-Producing Animals,” July 25, 2006. Available at <http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm052180.pdf> (accessed on March 19, 2016).
8. FDA, Memorandum to the File, from Director, Division of New Animal Drugs to Director, Bureau of Veterinary Medicine regarding NADA 41–061—Carbadox for Swine (September 22, 1972).
9. FDA, Memorandum to the File, S.H. Frazier, Jr., Division of Toxicology, to Director, Bureau of Veterinary Medicine, regarding Carbadox for Swine, August 27, 1970.
10. JECFA, Report on Carbadox, 1990. Available at <ftp://ftp.fao.org/ag/agn/jecfa/vetdrug/41-3-carbadox.pdf> (accessed on March 19, 2016).
11. FDA, Memorandum to the File, from Division of New Animal Drugs to Director, Bureau of Veterinary Medicine, regarding NADA 41–061, Carbadox for Swine (July 7, 1972).
12. FDA, Memorandum to the File, Approval of Original New Animal Drug Application NADA 92–955 (July 29, 1975).
13. Citizen Petition, Center for Science in the Public Interest, Docket No. FDA–1986–P–0299 (formerly 86P–0212), May 9, 1986.
14. FDA, Response to Citizen Petition, Center for Science in the Public Interest, Docket No. FDA–1986–P–0299 (formerly 86P–0212), May 30, 1995.
15. FDA, Memorandum to the File, from Residue Evaluation Branch, Division of Chemistry to Director, Division of

- Chemistry, regarding Review of Carbadox Metabolism (September 7, 1994).
16. FDA, Freedom of Information (FOI) Summary, NADA 041–061, MECADOX 10 (carbadox) Type A medicated article, supplemental approval October 5, 1998. Available at <http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm064223.htm> (accessed on March 19, 2016).
  17. FDA, Freedom of Information (FOI) Summary, NADA 141–211, MECADOX 10 (carbadox) and TERRAMYCIN 50, 100, or 200 (oxytetracycline) in Type C medicated feed, original approval July 21, 2004. Available at <http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm118005.pdf> (accessed on March 19, 2016).
  18. Codex Alimentarius Commission, Twenty-Eighth Session, Headquarters, Food and Agriculture Organization, Rome, Italy, 2005.
  19. FDA, CVM Guidance for Industry (GFI) #205, VICH GL 46, “Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Metabolism Study to Determine the Quantity and Identify the Nature of Residues (MRK),” September 15, 2011. Available at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM207939.pdf> (accessed on March 19, 2016).
  20. MacIntosh, A.I., G. Lauriault, and G.A. Neville, “Liquid Chromatographic Monitoring of the Depletion of Carbadox and its Metabolite Desoxycarbadox in Swine Tissues,” *Journal—Association of Official Analytical Chemists*, 68:665–71, 1985.
  21. FDA, CVM Guidance for Industry (GFI) #208, VICH GL 49, “Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Animals: Validation of Analytical Methods Used in Residue Depletion Studies,” September 15, 2011. Available at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM207942.pdf> (accessed on March 19, 2016).
  22. FDA, Memorandum to the File, Claycamp, H. G., Verification and Extension of the 2003 JECFA Carbadox Monograph Analyses, July 29, 2012.

Dated: April 6, 2016.

**Tracey Forfa,**

*Acting Director, Center for Veterinary Medicine.*

[FR Doc. 2016–08327 Filed 4–8–16; 11:15 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2014–E–1222]

**Determination of Regulatory Review Period for Purposes of Patent Extension; APOQUEL**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for APOQUEL and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that animal drug product.

**DATES:** Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by June 13, 2016. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 11, 2016. See “Petitions” in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you

do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA–2014–E–1222 for “Determination of Regulatory Review Period for Purposes of Patent Extension; APOQUEL.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access

the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA has approved for marketing the animal drug product APOQUEL

(ocloacitinib). APOQUEL is indicated for control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age. Subsequent to this approval, the USPTO received a patent term restoration application for APOQUEL (U.S. Patent No. 6,890,929) from Pfizer Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 11, 2015, FDA advised the USPTO that this animal drug product had undergone a regulatory review period and that the approval of APOQUEL represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

**II. Determination of Regulatory Review Period**

FDA has determined that the applicable regulatory review period for APOQUEL is 2,226 days. Of this time, 2,172 days occurred during the testing phase of the regulatory review period, while 54 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* April 12, 2007. FDA has verified the applicant's claim that the date the investigational new animal drug application (INAD) became effective was on April 12, 2007.

2. *The date the application was initially submitted with respect to the animal drug product under section 512 of the FD&C Act (21 U.S.C. 360b):* March 22, 2013. FDA has verified the applicant's claim that the new animal drug application (NADA) for APOQUEL (NADA 141-345) was submitted on March 22, 2013.

3. *The date the application was approved:* May 14, 2013. FDA has verified the applicant's claim that NADA 141-345 was approved on May 14, 2013.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,139 days of patent term extension.

**III. Petitions**

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination

(see **DATES**). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <http://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Dated: April 6, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-08333 Filed 4-11-16; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2014-E-2337]

**Determination of Regulatory Review Period for Purposes of Patent Extension; APTIOM**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for APTIOM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

**DATES:** Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by June 13, 2016. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 11, 2016. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2014-E-2337 for "Determination of Regulatory Review Period for Purposes of Patent Extension; APTIOM." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product APTIOM (eslicarbazepine acetate). APTIOM is indicated as an adjunctive treatment of partial-onset seizures. Subsequent to this approval, the USPTO received a patent term restoration application for APTIOM (U.S. Patent No. 5,753,646) from BIAL-PORTELA & CA, S.A., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 19, 2015, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of APTIOM represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

##### **II. Determination of Regulatory Review Period**

FDA has determined that the applicable regulatory review period for APTIOM is 2,517 days. Of this time, 832 days occurred during the testing phase of the regulatory review period, while 1,685 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* December 20, 2006. FDA has verified the BIAL-PORTELA & CA, S.A. claim that December 20, 2006, is the date the investigational new drug application became effective.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* March 30, 2009.

The applicant claims March 29, 2009 as the date the NDA for APTIOM was initially submitted. However, FDA records indicate that NDA 22-416 was submitted on March 30, 2009.

3. *The date the application was approved:* November 8, 2013. FDA has verified the applicant's claim that NDA 22-416 was approved on November 8, 2013.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 days of patent term extension.

### III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see DATES). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see DATES) and contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <http://www.regulations.gov> at Docket No. FDA-2013-S-0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: April 6, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-08334 Filed 4-11-16; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-D-1005]

#### Safety Considerations for Product Design To Minimize Medication Errors; Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the availability of a

guidance for industry entitled "Safety Considerations for Product Design to Minimize Medication Errors." The guidance is intended for sponsors of investigational new drug applications (INDs); applicants of new drug applications (NDAs), biologics licensing applications (BLAs), and abbreviated new drug applications (ANDAs); and manufacturers of prescription drugs marketed without an approved application or over-the-counter (OTC) monograph drugs. This guidance provides sponsors, applicants, and manufacturers with a set of principles to consider while developing drug products using a systems approach to minimize medication errors relating to product design and container closure design. The recommendations in this guidance document are intended to provide best practices on how to improve the drug product and container closure design for all prescription and nonprescription drug products. This guidance also provides examples of product designs that resulted in postmarketing error.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2012-D-1005 for "Safety Considerations for Product Design to Minimize Medication Errors." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the

“Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Irene Z. Chan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4420, Silver Spring, MD 20993-0002, 301-796-3962.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled “Safety Considerations for Product Design to Minimize Medication Errors.” The guidance is intended for sponsors of INDs; applicants of NDAs, BLAs, and ANDAs; and manufacturers of prescription drugs marketed without an approved application or OTC monograph drugs. This guidance provides sponsors, applicants, and manufacturers with a set of principles to consider while developing drug products using a systems approach to minimize medication errors relating to product design and container closure design. The recommendations in this guidance document are intended to provide best practices on how to improve the drug product and container closure design for all prescription and nonprescription drug products. The guidance also provides examples of product designs that resulted in postmarketing error.

This guidance document, which focuses on minimizing risks associated with the design of the drug product and its container closure system, is the first in a series of three planned guidances to minimize or eliminate hazards contributing to medication errors. The second guidance focuses on minimizing risks with the design of drug product container labels and carton labeling. The third guidance focuses on minimizing risks when developing and selecting proposed proprietary names for drugs.

In the **Federal Register** of December 13, 2012 (77 FR 74196), FDA announced the availability of the draft guidance

entitled “Safety Considerations for Product Design to Minimize Medication Errors.” The Agency has carefully reviewed and considered the comments it received in developing this final version of the guidance. The Agency has made revisions to the guidance to address public comments requesting clarifications and implement formatting changes for improved readability as it deemed appropriate. The Agency also moved recommendations appropriate for labels and labeling to a separate guidance. The guidance announced in this notice finalizes the draft guidance dated December 2012.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on addressing safety achieved through drug product design to minimize medication errors. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

**II. 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>.

**III. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910-0014. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910-0001. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910-0338.

**IV. Electronic Access**

You may obtain the document at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: April 6, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-08335 Filed 4-11-16; 8:45 am]

**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2016-D-0768]

**Donor Screening Recommendations To Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry; Availability; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of Monday, March 7, 2016 (81 FR 11808). The document announced a guidance for industry entitled “Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products.” The document was published with an incorrect docket number in the **ADDRESSES** section. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Lisa Granger, Office of Policy, Planning, Legislation, and Analysis, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993-0002, 301-796-9115.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2016-04893, appearing on page 11808 in the **Federal Register** of Monday, March 7, 2016, the following correction is made:

1. On page 11808, in the third column, the docket number is corrected to read “FDA-2016-D-0768”.

Dated: April 6, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-08330 Filed 4-11-16; 8:45 am]

**BILLING CODE 4164-01-P**



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0764]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Feed Regulatory Program Standards

**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 FDA's Animal Feed Regulatory Program Standards (AFRPS).

**DATES:** Submit either electronic or written comments on the collection of information by June 13, 2016.

**ADDRESSES:** You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2013-N-0764 for "Animal Feed Regulatory Program Standards." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments

received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@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.

#### Animal Feed Regulatory Program Standards—(OMB 0910-0760)—Extension

##### I. Background

In the United States, Federal and State Government Agencies ensure the safety of animal feed. FDA is responsible for ensuring that all food and feed moving in interstate commerce, except those

under the U.S. Department of Agriculture jurisdiction, are safe, wholesome, and labeled properly. States are responsible for conducting inspections and regulatory activities that help ensure food and feed produced, processed, and distributed within their jurisdictions are safe and in compliance with State laws and regulations. States primarily perform inspections under their own regulatory authority. Some States conduct inspections of feed facilities under contract with FDA. Because jurisdictions may overlap, FDA and States collaborate and share resources to protect animal feed.

The FDA Food Safety Modernization Act passed on January 4, 2011, calls for enhanced partnerships and provides a legal mandate for developing an Integrated Food Safety System (IFSS). FDA is committed to implementing an IFSS thereby optimizing coordination of food and feed safety efforts with Federal, State, local, tribal, and territorial regulatory and public health agencies. Model standards provide a consistent, underlying foundation that is critical for uniformity across State and Federal Agencies to ensure credibility of food and feed programs within the IFSS.

**II. Significance of Feed Program Standards**

The AFRPS provide a uniform and consistent approach to feed regulation in the United States. Implementation of the draft feed program standards is voluntary. States implementing the

standards will identify and maintain program improvements that will strengthen the safety and integrity of the U.S. animal feed supply.

The feed standards are the framework that each State should use to design, manage, and improve its feed program. The standards include the following: (1) Regulatory foundation; (2) training; (3) inspection program; (4) auditing; (5) feed-related illness or death and emergency response; (6) enforcement program; (7) outreach activities; (8) budget and planning; (9) assessment and improvement; (10) laboratory services; and (11) sampling program.

Each standard has a purpose statement, requirement summary, description of program elements, projected outcomes, and a list of required documentation. When a State program voluntarily agrees to implement the feed standards, it must fully implement and maintain the individual program elements and documentation requirements in each standard in order to fully implement the standard.

The feed standards package includes forms, worksheets, and templates to help the State program assess and meet the program elements in the standard. State programs are not obligated to use the forms, worksheets, and templates provided with the feed standards. Other manual or automated forms, worksheets, and templates may be used as long as the pertinent data elements are present. Records and other documents specified in the feed standards must be maintained in good order by the State

program and must be available to verify the implementation of each standard. The feed standards are not intended to address the performance appraisal processes that a State agency may use to evaluate individual employee performance.

In the first year of implementation, the State program uses the self-assessment worksheets to determine if the requirements for each standard are fully met, partially met, or not met. The self-assessments are used to develop an improvement plan for fully implementing the requirements of the 11 standards. Second and third-year assessments will provide progress evaluation.

Although FDA plans to provide financial support to State programs that implement the feed standards, funding opportunities are contingent upon the availability of funds. Funding opportunities may be only available to State feed regulatory programs that currently have an FDA feed inspection contract. State programs receiving financial support to implement the feed standards will be audited by FDA.

**III. Electronic Access**

Persons with access to the Internet may submit requests for a single copy of the current feed standards from [ORAHQOPIO@fda.hhs.gov](mailto:ORAHQOPIO@fda.hhs.gov). Please note that due to editorial revisions and public comments, the final standards may differ from the copy you receive.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

Type of respondent	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
State Employee .....	40	1	40	3,000	120,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden has been calculated to 3,000 hours per respondent. This burden was determined by capturing the average amount of time for each respondent to assess the current state of the program and work toward implementation of each of the 11 standards contained in AFRPS. FDA recognizes that full use and implementation of the feed standards by State feed programs will occur over many years and the number of years to fully implement the feed standards will vary among States.

Dated: April 6, 2016.  
**Leslie Kux,**  
*Associate Commissioner for Policy.*  
 [FR Doc. 2016-08331 Filed 4-11-16; 8:45 am]  
**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket Nos.: FDA-2014-E-2355; FDA-2014-E-2356; and FDA-2014-E-2357]

**Determination of Regulatory Review Period for Purposes of Patent Extension; GAZYVA**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for

GAZYVA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

**DATES:** Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by June 13, 2016.

Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 11, 2016. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets

Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket Nos. FDA-2014-E-2355; FDA-2014-E-2356; and FDA-2014-E-2357 for "Determination of Regulatory Review Period for Purposes of Patent Extension; GAZYVA."

Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents and the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301-796-3600.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product GAZYVA (obinutuzumab). GAZYVA is indicated, in addition with chlorambucil, for the treatment of patients with previously untreated chronic lymphocytic leukemia. Subsequent to this approval, the U.S. Patent and Trademark Office (USPTO) received patent term restoration applications for GAZYVA (U.S. Patent Nos. 6,602,684; 7,517,670; and 8,021,856) from Genentech, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated May 11, 2015, FDA advised the USPTO that this human biological product had undergone a

regulatory review period and that the approval of GAZYVA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

## II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for GAZYVA is 1,698 days. Of this time, 1,504 days occurred during the testing phase of the regulatory review period, while 194 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* March 11, 2009. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on March 11, 2009.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* April 22, 2013. FDA has verified the applicant's claim that the biologics license application (BLA) for GAZYVA (BLA 125486) was initially submitted on April 22, 2013.

3. *The date the application was approved:* November 1, 2013. FDA has verified the applicant's claim that BLA 125486 was approved on November 1, 2013.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 929, 946, or 484 days, respectively, of patent term extension.

## III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and ask for a redetermination (see **DATES**). Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must be timely (see **DATES**) and contain sufficient facts to merit an FDA investigation (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984). Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <http://www.regulations.gov> at Docket

No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: April 6, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–08338 Filed 4–11–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Global Affairs: Stakeholder Listening Session in Preparation for the 69th World Health Assembly

*Time and date:* May 6th, 2016, 10:30 a.m.–12:00 Noon EST.

*Place:* Hubert H. Humphrey Building, Room 505A, 200 Independence Ave. SW., Washington, District of Columbia 20201.

*Status:* Open, but requiring RSVP to [OGA.RSVP@hhs.gov](mailto:OGA.RSVP@hhs.gov).

*Purpose:* The U.S. Department of Health and Human Services (HHS)—charged with leading the U.S. delegation to the 69th World Health Assembly—will hold an informal Stakeholder Listening Session on *Friday, May 6, 10:30 a.m.–12:00 noon*, in Conference Room 505A of the Hubert H. Humphrey Building, 200 Independence Ave. S.W., Washington, DC 20201.

The Stakeholder Listening Session will help the HHS Office of Global Affairs prepare the U.S. delegation for the World Health Assembly by taking full advantage of the knowledge, ideas, feedback, and suggestions from all communities interested in and affected by agenda items to be discussed at the 69th World Health Assembly. Your input will contribute to U.S. positions as we negotiate with our international colleagues at the World Health Assembly these important health topics.

The listening session will be organized by agenda item, and participation is welcome from all individuals, particularly members of stakeholder communities, including:

- Public health and advocacy groups;
- State, local, and Tribal groups;
- Private industry;
- Minority health organizations; and
- Academic and scientific organizations.

All agenda items to be discussed at the 69th World Health Assembly can be found at this Web site: [http://apps.who.int/gb/ebwha/pdf\\_files/WHA69/A69\\_1-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_1-en.pdf).

*RSVP:* Due to security restrictions for entry into the HHS Hubert H. Humphrey

Building, we will need to receive RSVPs for this event. Please send your full name and organization to [OGA.RSVP@hhs.gov](mailto:OGA.RSVP@hhs.gov). If you are *not* a U.S. citizen, please note this in the subject line of your RSVP, and our office will contact you to gain additional biographical information for your clearance. Please RSVP no later than Wednesday, April 27, 2016.

Written comments are welcome and encouraged, even if you are planning on attending in person. Please send these to the email address: [OGA.RSVP@hhs.gov](mailto:OGA.RSVP@hhs.gov).

We look forward to hearing your comments relative to the 69th World Health Assembly agenda items.

Dated: March 14, 2016.

**Jimmy Kolker,**

*Assistant Secretary for Global Affairs.*

[FR Doc. 2016–08287 Filed 4–11–16; 8:45 am]

**BILLING CODE 4150–38–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Announcement of Establishment of the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030 and Solicitation of Nominations for Membership; Correction

**AGENCY:** Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, U.S. Department of Health and Human Services.

**ACTION:** Notice; correction.

**SUMMARY:** The U.S. Department of Health and Human Services published a notice in the **Federal Register**, dated March 17, 2016, to announce the establishment of the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030 (Committee) and invites nominations for membership. This notice contained incorrect information.

**FOR FURTHER INFORMATION CONTACT:** Emmeline Ochiai, email address: [HP2030@hhs.gov](mailto:HP2030@hhs.gov).

#### Correction

In the **Federal Register**, dated March 17, 2016, on page 14455, correct the Title to read:

Announcement of Intent to Establish the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030 and Solicitation of Nominations for Membership and correct the **SUMMARY** to read:

**SUMMARY:** The U.S. Department of Health and Human Services (HHS) announces its intent

to establish the Secretary's Advisory Committee on National Health Promotion and Disease Prevention Objectives for 2030 (Committee) and invites nominations for membership.

Dated: April 5, 2016.

**Donald Wright,**

*Deputy Assistant Secretary for Health,  
(Disease Prevention and Health Promotion).*

[FR Doc. 2016-08284 Filed 4-11-16; 8:45 am]

**BILLING CODE 4150-32-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Temporary Reassignment of State, Tribal, and Local Personnel During a Public Health Emergency; Correction

**AGENCY:** Department of Health and Human Services (HHS), Office of the Secretary.

**ACTION:** Notice, correction.

**SUMMARY:** This document corrects one technical error that appeared in the final guidance published in the **Federal Register** on April 1, 2016 (81 OFR 18865), entitled "Temporary Reassignment of State, Tribal, and Local Personnel During a Public Health Emergency."

**DATES:** This correction is effective on April 12, 2016.

**ADDRESSES:** Copy of the final guidance may be obtained at [www.PHE.gov/TemporaryReassignment](http://www.PHE.gov/TemporaryReassignment).

**FOR FURTHER INFORMATION CONTACT:** For additional information, please contact: Sally Phillips, RN, Ph.D., Deputy Assistant Secretary, Office of Policy and Planning, Office of the Assistant Secretary for Preparedness and Response, 200 Independence SW., Washington, DC 20004.

#### SUPPLEMENTARY INFORMATION:

*Correction:* In FR Doc. 16-07404, published on April 1, 2016, (81 FR 18865) make the following correction. On page 18865, in the second column, correct the Web site address to read: [www.PHE.gov/TemporaryReassignment](http://www.PHE.gov/TemporaryReassignment).

Dated: April 6, 2016.

**Wilma Robinson,**

*Deputy Executive Secretary to the  
Department, U.S. Department of Health and Human Services.*

[FR Doc. 2016-08289 Filed 4-11-16; 8:45 am]

**BILLING CODE 4150-37-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; Program Project: Animal/Biological Resource Facilities.

*Date:* April 20, 2016.

*Time:* 11:30 a.m. to 12:30 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:* Serena Chu, Ph.D., Scientific Review Officer, BBBP IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3178, MSC 7848, Bethesda, MD 20892, 301-500-5829, [sechu@csr.nih.gov](mailto:sechu@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Memory and Stress.

*Date:* April 22, 2016.

*Time:* 12:30 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:* Jasenka Borzan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892-7814, 301-435-1787, [borzanj@csr.nih.gov](mailto:borzanj@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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: April 5, 2016.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2016-08290 Filed 4-11-16; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Board on Medical Rehabilitation Research.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* National Advisory Board on Medical Rehabilitation Research.

*Date:* May 2-3, 2016.

*Time:* May 2, 2016, 9:00 a.m. to 5:00 p.m.

*Agenda:* NICHD and NCMRR Director's reports; NICHD training activities; Review of Cerebral Palsy workshop; Operationalizing NIH rehabilitation research plan.

*Place:* Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

*Time:* May 3, 2016, 8:30 a.m. to 12:00 p.m.

*Agenda:* Common data elements in rehabilitation research; Promoting rehabilitation research grant applications.

*Place:* Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

*Contact Person:* Ralph M. Nitkin, Ph.D., Deputy Director, National Center for Medical Rehabilitation Research (NCMRR), Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, DHHS, 6100 Executive Boulevard, Room 2A03, Bethesda, MD 20892-7510, (301) 402-4206, [rn21e@nih.gov](mailto:rn21e@nih.gov).

Information is also available on the Institute's/Center's home page: <http://www.nichd.nih.gov/about/advisory/nabmrr/Pages/index.aspx> where the current roster and minutes from past meetings are posted. (Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: April 6, 2016.

**Anna Snouffer,**

*Deputy Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2016-08294 Filed 4-11-16; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Fogarty International Center; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Fogarty International Center Advisory Board. The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, 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:* Fogarty International Center Advisory Board.

*Date:* May 10–11, 2016.

*Closed:* May 10, 2016.

*Time:* 1:00 p.m. to 5:00 p.m.

*Agenda:* Second level review of grant applications.

*Place:* National Institutes of Health, Stone House, Building 16, Conference Room, 9000 Rockville Pike, Bethesda, MD 20892.

*Open:* May 11, 2016.

*Time:* 9:00 a.m. to 3:00 p.m.

*Agenda:* Update and discussion of current and planned FIC activities, including an overview and presentations from grantees of our Global Environmental and Occupational Health (GEOHealth) Program.

*Place:* National Institutes of Health, Stone House, Building 16, Conference Room, 9000 Rockville Pike, Bethesda, MD 20892.

*Contact Person:* Kristen Weymouth, Executive Secretary, Fogarty International Center, National Institutes of Health, 31 Center Drive, Room B2C02, Bethesda, MD 20892, (301) 496-1415, [weymouthk@mail.nih.gov](mailto:weymouthk@mail.nih.gov).

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on

this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <http://www.fic.nih.gov/About/Advisory/Pages/default.aspx>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.106, Minority International Research Training Grant in the Biomedical and Behavioral Sciences; 93.154, Special International Postdoctoral Research Program in Acquired Immunodeficiency Syndrome; 93.168, International Cooperative Biodiversity Groups Program; 93.934, Fogarty International Research Collaboration Award; 93.989, Senior International Fellowship Awards Program, National Institutes of Health HHS)

Dated: April 6, 2016.

**Natasha M. Copeland,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2016-08292 Filed 4-11-16; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; 30-day Comment Request; The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Diseases Among Men and Women in Agriculture (NIEHS)

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 27, 2015, Pages 74115–74116, and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information

collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

*Direct Comments to OMB:* Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974, Attention: NIH Desk Officer.

*Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

**FOR FURTHER INFORMATION CONTACT:** To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Dale Sandler, Ph.D., Chief, Epidemiology Branch, National Institute of Environmental Health Sciences, NIH, 111 T.W. Alexander Drive, P.O. Box 12233, MD A3-05, Research Triangle Park, NC 27709, or call non-toll-free number 919-541-4668, or email your request, including your address to: [sandler@niehs.nih.gov](mailto:sandler@niehs.nih.gov). Formal requests for additional plans and instruments must be requested in writing.

*Proposed Collection:* The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Diseases Among Men and Women in Agriculture, 0925-0406 (Expiration Date 9/30/2016, REVISION), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

*Need and Use of Information Collection:* The purpose of this information collection is to request new components as part of the ongoing Study of Biomarkers of Exposures and Effects in Agriculture (BEEA), as well as continue and complete phase IV (2013–2016) of the Agricultural Health Study (AHS) and continue buccal cell collection. Phase IV will continue to update the occupational and environmental exposure information as well as medical history information for licensed pesticide applicators and their spouses enrolled in the AHS. The new BEEA components are a control respondent group, and a smartphone application (app), along with new sample collection (buccal cell and air monitoring samples). The new components will use similar procedures to ones already employed on the BEEA study, as well as other NCI studies. The primary objectives of the study are to determine the health effects resulting

from occupational and environmental exposures in the agricultural environment. Secondary objectives include evaluating biological markers that may be associated with agricultural exposures and risk of certain types of cancer. Phase IV questionnaire data are collected by using self-administered computer assisted web survey (CAWI); self-administered paper-and-pen (Paper/pen); or an interviewer administered computer assisted telephone interview

(CATI) and in-person interview (CAPI) systems for telephone screeners and home visit interviews, respectively. Some respondents are also asked to participate in the collection of biospecimens and environmental samples, including blood, urine, buccal cells (loose cells from the respondent's mouth), and vacuum dust. The findings will provide valuable information concerning the potential link between agricultural exposures and cancer and

other chronic diseases among Agricultural Health Study cohort members, and this information may be generalized to the entire agricultural community.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 11,440.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Private and Commercial Applicators and Spouses.	IA/NC Scripts for Verbal Consent for Buccal .....	100	1	3/60	5
Private and Commercial Applicators and Spouses.	IA/NC Written Consent for Buccal .....	100	1	5/60	8
Private and Commercial Applicators and Spouses.	Buccal Follow-up Scripts (as needed): Reminder, Missing Consent, or Damaged/Missing Sample.	30	1	2/60	1
Private Applicators .....	BEEA CATI Screening Script for RSG, REG or AMG Eligibility.	480	1	20/60	160
Private Applicators .....	IA/NC BEEA Consent for RSG Home Visit or REG Home Visit or AMG Home Visit.	196	1	5/60	16
Private Applicators .....	IA/NC BEEA RSG Pre-Visit Show Card .....	160	1	5/60	13
Private Applicators .....	IA/NC BEEA RSG Paper/Pen Dust Questionnaire .....	160	1	10/60	27
Private Applicators .....	BEEA RSG Pre-Home Visit Script .....	160	1	2/60	5
Private Applicators .....	BEEA RSG Home Visit CAPI, Blood, Buccal cell, Urine & Dust.	160	1	90/60	240
Private Applicators .....	IA/NC BEEA REG Pre-Visit Show Card .....	20	3	5/60	5
Private Applicators .....	IA/NC BEEA REG Paper/Pen Dust Questionnaire .....	20	3	10/60	10
Private Applicators .....	BEEA REG Pre-Home Visit Script .....	20	3	2/60	2
Private Applicators .....	BEEA REG Home Visit CAPI, Blood, Buccal cell, Urine & Dust.	20	3	90/60	90
Private Applicators .....	IA/NC BEEA REG Post-Exposure Scheduling Script ....	20	1	2/60	1
Private Applicators .....	IA/NC BEEA AMG Pre-Visit Show Card .....	16	2	5/60	3
Private Applicators .....	IA/NC BEEA AMG Paper/Pen Dust Questionnaire .....	16	2	10/60	5
Private Applicators .....	BEEA AMG Pre-Home Visit Script .....	16	2	2/60	1
Private Applicators .....	BEEA AMG Home Visit CAPI, Blood, Urine, Buccal cell & Dust.	16	2	90/60	48
Private Applicators .....	IA/NC BEEA Consent for AMG Farm Visit .....	16	1	5/60	3
Private Applicators .....	BEEA Pre-Farm Visit Script .....	16	2	2/60	1
Controls .....	BEEA CATI Control Eligibility Script .....	215	1	20/60	72
Controls .....	IA/NC BEEA Control Home Visit Consent .....	67	1	5/60	6
Controls .....	IA/NC BEEA Pre-Visit Show Card .....	67	1	5/60	6
Controls .....	IA/NC BEEA Paper/Pen Dust Questionnaire .....	67	1	10/60	11
Controls .....	BEEA REG Pre-Visit Script .....	67	1	2/60	2
Controls .....	BEEA Control Home Visit CAPI, Blood, Buccal cell, Urine, & Dust.	67	1	90/60	101
Private Applicators .....	'Life in a Day' Smartphone App Consent and Setup ....	78	1	20/60	26
Private Applicators .....	'Life in a Day' Smartphone Application .....	78	30	10/60	390
Private Applicators .....	Phase IV Follow-up CAWI, CATI, or Paper/pen .....	13,855	1	25/60	5,773
Spouses .....	Phase IV Follow-up CAWI, CATI, or Paper/pen .....	10,201	1	25/60	4,250
Proxy .....	Phase IV Follow-up CAWI, CATI, or Paper/pen .....	635	1	15/60	159
<b>Total .....</b>		<b>27,139</b>	<b>29,641</b>		<b>11,440</b>

Dated: April 4, 2016.  
**Jane M. Lambert,**  
*Project Clearance Liaison, CIP, NIEHS.*  
 [FR Doc. 2016-08397 Filed 4-11-16; 8:45 am]  
**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**National Institutes of Health**  
**National Institute on Aging; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial

property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Aging Special Emphasis Panel; Biomarkers for AD: The Adult Children Study II.

*Date:* May 3, 2016.

*Time:* 10:30 a.m. to 1:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Maurizio Grimaldi, MD, Ph.D., Scientific Review Officer, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Room 2C218, Bethesda, MD 20892, 301-496-9374, [grimaldim2@mail.nih.gov](mailto:grimaldim2@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: April 6, 2016.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2016-08293 Filed 4-11-16; 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 Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; AIDS and Related Research: Clinical Applications Member Conflicts.

*Date:* April 20-21, 2016.

*Time:* 10:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Robert Freund, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, 301-435-1050, [freundr@csr.nih.gov](mailto:freundr@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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: April 6, 2016.

**Natasha M. Copeland,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2016-08291 Filed 4-11-16; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

[FWS-R8-ES-2016-N032;  
FXES1112080000-167-FF08ECAR00]

#### Endangered and Threatened Wildlife and Plants; Application To Amend Incidental Take Permit; Revised Diversified Pacific Low-Effect Habitat Conservation Plan and Associated Documents, City of Redlands, San Bernardino County, California

**ACTION:** Notice of availability; request for comments.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), have received an application from Diversified Pacific (applicant), to amend a 5-year incidental take permit (permit). The application includes the applicant's revised habitat conservation plan (HCP), as required by the Endangered Species Act of 1973, as amended (Act). If approved, the amended permit would authorize incidental take of the endangered San Bernardino Merriam's kangaroo rat (SBKR) in the course of routine construction activities associated with the development of residential houses in the City of Redlands. We invite public comment on the application for a permit amendment and the revised HCP, and on our preliminary determination that the revised HCP continues to qualify as "low-effect" for a categorical exclusion under the National Environmental Policy Act. To make this determination we used our low-effect screening form.

**DATES:** To ensure consideration, please send your written comments by May 12, 2016.

**ADDRESSES:** You may request a copy of the amended permit application, the

low-effect screening form, and/or the revised HCP by email, telephone, fax, or U.S. mail (see below). These documents are also available for public inspection by appointment during normal business hours at the office below. Please send your requests or comments by any one of the following methods, and specify "Diversified Pacific Low-Effect HCP" in your request or comment.

• *Email:* [karin\\_cleary-rose@fws.gov](mailto:karin_cleary-rose@fws.gov).

Include "Diversified Pacific Low-Effect HCP" in the subject line of your message.

• *Telephone:* Karin Cleary-Rose, Palm Springs Fish and Wildlife Office, 760-322-2070 extension 206.

• *Fax:* Karin Cleary-Rose, Palm Springs Fish and Wildlife Office, 760-322-4648, Attn.: Diversified Pacific Low-Effect HCP.

• *U.S. Mail:* Karin Cleary-Rose, Palm Springs Fish and Wildlife Office, Attn.: Diversified Pacific Low-Effect HCP, U.S. Fish and Wildlife Service, 777 East Tahquitz Canyon Way, Suite 208, Palm Springs, California 92262.

• *In-Person Viewing or Pickup of Documents, or Delivery of Comments:* Call 760-322-2070 to make an appointment during regular business hours at the above address.

#### FOR FURTHER INFORMATION CONTACT:

Karin Cleary-Rose, Inland Division Chief, Palm Springs Fish and Wildlife Office; telephone 760-322-2070 extension 206. If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at 800-877-8339.

#### SUPPLEMENTARY INFORMATION:

##### Introduction

The Service issued an incidental take permit under section 10(a)(1)(B) of the Act to the applicant, Diversified Pacific, on August 21, 2015. The permit authorizes the applicant to take SBKR as a result of permanent impacts to 7.7 acres of habitat that the species uses for breeding, feeding, and sheltering. Take of SBKR is incidental to the applicant's activities associated with the construction of residential houses in the City of Redlands, San Bernardino County, California. The site is located southwest and southeast of the intersection of Pioneer Avenue and Judson Street in the City of Redlands, San Bernardino County, California. The proposed project site is surrounded by residential development and a mix of active and abandoned citrus orchards. An active municipal airport is located approximately 0.25 mile northeast of the project site.

The original permit required the applicant to mitigate impacts to the



SBKR by translocating HCP individuals (up to approximately 38 individuals) to a conserved property within the Santa Ana River watershed, monitoring those translocated individuals for 5 years, and funding the perpetual management of 20.9 acres of high-quality SBKR habitat at the conserved 100-acre Redlands Conservancy property in Redlands, California. The applicant captured 41 SBKR from 4.4 acres before commencement of ground disturbance on the project site and translocated them to an area of the Cajon Creek Conservation Bank in the City of Muscoy, San Bernardino County, California, where they augmented a low-density population of SBKR. These animals will be monitored for 5 years, including annual reporting.

The applicant requests a permit amendment to expand the SBKR translocation program permitted in the HCP to allow for additional capture and translocation of SBKR from the project site to a Service-approved receiver site as described in the revised HCP. Upon inspection of the remaining undeveloped areas within the permit area, the SBKR biologist determined that 9.7 acres may still be occupied, for a total of 14.1 acres of occupied SBKR habitat. To minimize impacts associated with the expanded translocation program, the applicant will provide funding for the perpetual management and monitoring of 7.3 acres of additional occupied high-quality SBKR habitat in the City of Redlands, owned and conserved by the Redlands Land Conservancy into perpetuity as part of the revised HCP. This increase in the SBKR population across a larger portion of the permit area was unexpected given the overall poor quality of the conditions onsite and the limited number of SBKR previously trapped. The abnormally wet 2015 summer season allowed for increased seed production of summer annual plants. In turn, the SBKR on the project site experienced high reproductive success, which led to an expansion of distribution of SBKR on the site. Because the project site is within an urban matrix and physically isolated from other areas that support SBKR, the project site still does not provide long-term conservation value for the species. Pursuant to the terms of the original permit, the applicant prepared a management plan for and provided financial assurances for long-term funding of the management of 20.9 acres of high-value SBKR conservation land at the Redlands Conservancy Conservation Area. Under the permit amendment, the applicant would fund an endowment

account for management of an additional 7.3 acres of Conservancy lands, for a total of 28.2 acres of Conservancy lands with high-value SBKR land protected and managed in perpetuity.

We published a final rule to list SBKR as endangered on September 24, 1998 (63 FR 51005). The rule became effective September 24, 1998. Final designation of critical habitat was published on April 23, 2002 (67 FR 19812). A 5-year review of the species was published on May 21, 2010 (75 FR 28636).

### Background

Section 9 of the Act (16 U.S.C. 1531–1544 *et seq.*) and Federal regulations (50 CFR 17) prohibit the taking of fish and wildlife species listed as endangered or threatened under section 4 of the Act. Take of federally listed fish or wildlife is defined under the Act as to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect listed species, or attempt to engage in such conduct. The term “harass” is defined in the regulations as to carry out actions that create the likelihood of injury to listed species to such an extent as to significantly disrupt normal behavioral patterns, which include, but are not limited to, breeding, feeding, or sheltering (50 CFR 17.3). The term “harm” is defined in the regulations as significant habitat modification or degradation that results in death or injury of listed species by significantly impairing essential behavioral patterns, including breeding, feeding, or sheltering (50 CFR 17.3). However, under specified circumstances, the Service may issue permits that allow the take of federally listed species, provided that the take that occurs is incidental to, but not the purpose of, an otherwise lawful activity.

Regulations governing incidental take permits for threatened and endangered species are at 50 CFR 17.32 and 17.22, respectively. In addition to meeting other criteria, activities covered by an incidental take permit must not jeopardize the continued existence in the wild of federally listed wildlife or plants.

### Applicant's Proposal

The applicant requests an amendment to the 5-year permit under section 10(a)(1)(B) of the Act to allow for expanded translocation of SBKR from the project site to high-quality habitat receiver sites. Upon issuance of the current permit, and as a condition of construction within the project area, the SBKR biologist trapped 4.4 acres of the estimated 7.7 acres of occupied habitat

and discontinued trapping as the maximum take of SBKR had occurred. Upon further inspection, the SBKR biologist determined that 9.7 acres of undeveloped portions of the project area remained occupied by SBKR, for a total of 14.1 acres of occupied SBKR habitat.

We think that the abnormally wet 2015 summer season allowed for increased seed production of summer annual plants. In turn, the SBKR on the project site experienced high reproductive success and recruitment of juveniles, which increased the total numbers of individuals on the site and led to an expansion of distribution of SBKR on the site. Because the project site is within an urban matrix and physically isolated from other areas that support SBKR, we still believe that the project site does not provide long-term conservation value for the species.

If we approve the permit, the applicant would translocate all remaining SBKR to other Service-approved receiver sites from the remaining undeveloped portion of property as identified in the revised HCP. Translocation of SBKR from the project site is a requirement under the current permit as mitigation for impacts to SBKR, and it is recognized that moving the species off of the project site, which provides no connectivity to other SBKR populations, to approved receiver sites is a conservation benefit to the species. To mitigate take of SBKR at the project site, the applicant proposes the following mitigation strategy:

1. All SBKR captured prior to ground disturbance on the project site will be translocated to one or more Service-approved receiver sites in the Santa Ana River Watershed. These animals will be monitored for 5 years, including annual reporting.

2. The applicant will provide funding for the perpetual management and monitoring of 7.3 acres of additional high-quality occupied SBKR habitat in the City of Redlands, owned and conserved by the Redlands Land Conservancy into perpetuity as part of the revised HCP. In total for both the original HCP and the revised HCP, the applicant will fund the perpetual management and monitoring of 28.2 acres of SBKR habitat.

### Proposed Habitat Conservation Plan Alternatives

In the revised HCP, the applicant considers alternatives to the taking of SBKR under the proposed action. Our proposed action is to issue an amended permit to the applicant, who would implement the revised HCP. If we approve the amended permit, additional take of SBKR would be authorized for

the applicant's construction activities associated with the development of residential houses in the City of Redlands. The applicant's revised HCP identifies a no-build alternative that would not result in additional incidental take of SBKR; however, it is infeasible for the applicant to accept this alternative, as it would result in no development of the land and associated infrastructure improvements necessary to the City of Redlands and surrounding community. The revised HCP also examined participation in a regional HCP as an alternative to an individual HCP. This alternative plan is infeasible because there is currently no completed regional plan, and the timing for completion of a regional plan is unknown.

### Our Preliminary Determination

We invite comments on our preliminary determination that our proposed action, based on the applicant's proposed activities to expand SBKR translocation minimization and mitigation measures, would have a minor or negligible effect on SBKR, and that the revised HCP qualifies as "low effect" as defined by our *Habitat Conservation Planning Handbook* (November 1996).

We base our determination that this HCP qualifies as a low-effect plan on the following three criteria:

1. Implementation of the HCP would result in minor or negligible effects on federally listed, proposed, and candidate species and their habitats;
2. Implementation of the HCP would result in minor or negligible effects on other environmental values or resources; and
3. Impacts of the HCP, considered together with the impacts of other past, present, and reasonably foreseeable similarly situated projects, would not result, over time, in cumulative effects to environmental values or resources that would be considered significant.

As more fully explained in our associated low-effect screening form, the applicant's revised HCP qualifies as a low-effect HCP for the following reasons:

1. The project is small in size and the loss of this habitat would not jeopardize the continued existence of the SBKR.
2. The project site is not in designated critical habitat for the SBKR.
3. The translocation of additional SBKR off of the project site to conserved receiver sites would increase the local genetic diversity of SBKR at multiple locations in the Santa Ana River watershed, contributing to species recovery.

Therefore, our proposed issuance of the requested incidental take permit qualifies as a categorical exclusion under the National Environmental Policy Act, as provided by Department of the Interior implementing regulations in part 46 of title 43 of the Code of Federal Regulations (43 CFR 46.205, 46.210, and 46.215). Based on our review of public comments we receive in response to this notice, we may revise this preliminary determination.

### Public Review

The Service invites the public to comment on the application to amend the permit, including the revised HCP, during the public comment period. Copies of the documents will be available during a 30-day public comment period (see **DATES**). If you wish to comment, you may submit your comments to the address listed in **ADDRESSES**. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may 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.

### Next Steps

We will evaluate the revised HCP and comments we receive to determine whether the application for a permit amendment meets the requirements and issuance criteria under section 10(a) of the Act (16 U.S.C. 1531 *et seq.*). We will also evaluate whether issuance of an amended section 10(a)(1)(B) incidental take permit would comply with section 7 of the Act by reinitiating intra-Service consultation. We will use the results of the reinitiation, in combination with the above findings, in our final analysis to determine whether or not to issue a permit amendment. If the requirements and issuance criteria under section 10(a) are met, we will issue the permit amendment to the applicant for incidental take of SBKR associated with expanded translocation activities.

### Scott A. Sobiech,

*Acting Field Supervisor, Carlsbad Fish and Wildlife Office, Carlsbad, California.*

[FR Doc. 2016-08345 Filed 4-11-16; 8:45 am]

**BILLING CODE 4333-15-P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

[FWS-R8-ES-2016-N049;  
FXES1113080000-167-FF08ENVS00]

### Application for an Enhancement of Survival Permit for the Proposed Springs Preserve Safe Harbor Agreement, Las Vegas, Clark County, Nevada

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of availability; receipt of application and request for comment.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), have received an application from the Las Vegas Valley Water District (applicant) for an enhancement of survival permit under the Endangered Species Act of 1973, as amended (Act). The permit application includes a proposed safe harbor agreement (SHA) between the applicant and the Service. The SHA provides for voluntary activities that will contribute to the recovery of the Pahrump poolfish. We have made a preliminary determination that the proposed SHA and permit application are eligible for categorical exclusion under the National Environmental Policy Act of 1969 (NEPA).

**DATES:** Written comments must be received on or before May 12, 2016.

**ADDRESSES:** Comments should be addressed to Michael J. Senn, Field Supervisor, by U.S. mail at Southern Nevada Fish and Wildlife Office, 4701 North Torrey Pines Drive, Las Vegas, NV 89130; or by fax to 702-515-5231 (see Public Review and Comment under **SUPPLEMENTARY INFORMATION**).

**FOR FURTHER INFORMATION CONTACT:** James Harter, Fish Biologist, at the Southern Nevada Fish and Wildlife Office address, or by telephone at 702-515-5230.

**SUPPLEMENTARY INFORMATION:** We have received an application from the Las Vegas Valley Water District (applicant) for an enhancement of survival permit under the Endangered Species Act of 1973, as amended (Act; 16 U.S.C. 1531 *et seq.*). The permit application includes a proposed safe harbor agreement (SHA) between the applicant and the Service. The SHA provides for voluntary habitat restoration, maintenance, enhancement, or creation activities that will contribute to the recovery of the Pahrump poolfish (*Empetrichthys latos*). The proposed duration of both the SHA and permit is for 15 years, with an option to extend an additional 15 years.

We have made a preliminary determination that the proposed SHA and permit application are eligible for categorical exclusion under the National Environmental Policy Act of 1969 (NEPA). The basis for this determination is contained in an environmental Action Statement, which is also available for public review.

### Background

The primary objective of this SHA is to encourage voluntary creation and maintenance of habitat to benefit the Pahrump poolfish by assuring the property owners that they will not be subjected to increased property use restrictions as a result of their efforts to establish a population of a listed species on their property, to increase the distribution and number of refugia within the range of the listed species. Application requirements and issuance criteria for enhancement of survival permits through SHAs are found in 50 CFR 17.22 and 17.32(c). As long as the enrolled landowner allows the agreed-upon conservation measures to be completed on their property and maintains their baseline responsibilities, they may make any other lawful use of the property during the permit term, even if such use results in the take of individual Pahrump poolfish or harm to their habitat as described in the SHA.

The landowner has suitable habitat for the establishment of a refugium that will contribute to the conservation of the species. The applicant has provided a SHA to the Service that includes: (1) A map of the property and its legal description; (2) a description of existing biological community, including nonnative aquatic species and sensitive or protected species; (3) the portion of the property to be enrolled and its acreage; (4) a description of the habitat types that occur on the property to be enrolled, including a description of the ponds and other aquatic habitats; and (5) current land use practices and existing developments, and the characteristics of water supplies to aquatic habitats.

The applicant, as the permittee, will be responsible for annual monitoring and reporting related to implementation of the SHA and fulfillment of their provisions. As specified in the SHA, the applicant will issue yearly reports to the Service related to implementation of the program.

Therefore, we have made a preliminary determination that our proposed issuance of the requested permit qualifies as a categorical exclusion under the National Environmental Policy Act, as provided by Department of the Interior

implementing regulations in part 46 of title 43 of the Code of Federal Regulations (43 CFR 46.205, 46.210, and 46.215), based on the following criteria: (1) Implementation of the SHA would result in minor or negligible effects on federally listed, proposed, and candidate species and their habitats; (2) implementation of the SHA would result in minor or negligible effects on other environmental values or resources; and (3) impacts of the SHA, considered together with impacts of other past, present, and reasonably foreseeable similarly situated projects, would not result, over time, in cumulative effects to environmental values or resources that would be considered significant. This is more fully explained in our environmental action statement.

Based upon this preliminary determination, we do not intend to prepare further NEPA documentation. We will consider public comments in making our final determination on whether to prepare such additional documentation.

### Public Review and Comments

Individuals wishing copies of the permit application, the environmental action statement, or copies of the full text of the SHA, including a map of the proposed permit area, references, and legal descriptions of the proposed permit area, should contact the office and personnel listed in the **FOR FURTHER INFORMATION CONTACT** section or obtain copies from our Web site, <http://www.fws.gov/nevada>. Documents also will be available for public inspection, by appointment, during normal business hours at our office (see **ADDRESSES**).

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

### Decision

We will evaluate the permit application, the SHA, and comments submitted thereon to determine whether the application meets the requirements of section 10(a) of the Act and NEPA regulations. If the requirements are met, the Service will sign the proposed SHA and issue an enhancement of survival permit under section 10(a)(1)(A) of the Act to the applicant for take of the Pahrump poolfish incidental to

otherwise lawful activities of the project. We will not make a final decision until after the end of the 30-day comment period, and we will fully consider all comments received during the comment period.

### Authority

We provide this notice under section 10(c) of the Act (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.22 and 17.32), and the National Environmental Policy Act (42 U.S.C. 4371 *et seq.*) and its implementing regulations (40 CFR 1506.6).

Dated: March 31, 2016.

**Michael J. Senn,**

*Field Supervisor, Southern Nevada Fish and Wildlife Office, Las Vegas, Nevada.*

[FR Doc. 2016-08344 Filed 4-11-16; 8:45 am]

**BILLING CODE 4333-15-P**

## INTERNATIONAL TRADE COMMISSION

### Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Portable Electronic Devices and Components Thereof, DN 3130*; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing under section 210.8(b) of the Commission's Rules of Practice and Procedure (19 CFR 210.8(b)).

**FOR FURTHER INFORMATION CONTACT:** Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205-2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at EDIS,<sup>1</sup> and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205-2000.

General information concerning the Commission may also be obtained by accessing its Internet server at United States International Trade Commission

<sup>1</sup> Electronic Document Information System (EDIS): <http://edis.usitc.gov>.

(USITC) at USITC.<sup>2</sup> The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at EDIS.<sup>3</sup> Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

**SUPPLEMENTARY INFORMATION:** The Commission has received a complaint and a submission pursuant to section 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Creative Labs, Inc. on March 24, 2016. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain portable electronic devices and components thereof. The complaint names as respondents ZTE Corporation of China; ZTE (USA) Inc. of Richardson, TX; Sony Corporation of Japan; Sony Mobile Communications, Inc. of Japan; Sony Mobile Communications AB of Sweden; Sony Mobile Communications (USA), Inc. of Atlanta, GA; Samsung Electronics Co., Ltd. of Korea; Samsung Electronics America, Inc. of Ridgefield Park, NJ; Samsung Telecommunications America, LLC of Richardson, TX; LG Electronics, Inc. of Korea; LG Electronics U.S.A., Inc. of Englewood Cliffs, NJ; LG Electronics Mobilecomm U.S.A., Inc. of San Diego, CA; Lenovo Group Ltd. of China; Lenovo (United States) Inc. of Morrisville, NC; Motorola Mobility LLC of Chicago, IL; HTC Corporation of Taiwan; HTC America, Inc. of Bellevue, WA; Blackberry Ltd. of Canada; and Blackberry Corporation of Irving, TX. The complainant requests that the Commission issue a limited exclusion order and cease and desist orders, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or section 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive

conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

- (i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;
- (ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;
- (iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;
- (iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and
- (v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number ("Docket No. 3130") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, Electronic Filing Procedures.)<sup>4</sup> Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such

treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.<sup>5</sup>

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: March 24, 2016.

**Lisa R. Barton,**

*Secretary to the Commission.*

[FR Doc. 2016-08325 Filed 4-11-16; 8:45 am]

**BILLING CODE 7020-02-P**

## INTERNATIONAL TRADE COMMISSION

### Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

**AGENCY:** U.S. International Trade Commission.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Digital Video Receivers and Hardware and Software Components Thereof, DN 3135*; the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing under section 210.8(b) of the Commission's Rules of Practice and Procedure (19 CFR 210.8(b)).

**FOR FURTHER INFORMATION CONTACT:** Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205-2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at EDIS,<sup>1</sup> and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205-2000.

General information concerning the Commission may also be obtained by accessing its Internet server at United States International Trade Commission

<sup>2</sup> United States International Trade Commission (USITC): <http://edis.usitc.gov>.

<sup>3</sup> Electronic Document Information System (EDIS): <http://edis.usitc.gov>.

<sup>4</sup> Handbook for Electronic Filing Procedures: [http://www.usitc.gov/secretary/fed\\_reg\\_notices/rules/handbook\\_on\\_electronic\\_filing.pdf](http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf).

<sup>5</sup> Electronic Document Information System (EDIS): <http://edis.usitc.gov>.

<sup>1</sup> Electronic Document Information System (EDIS): <http://edis.usitc.gov>.

(USITC) at USITC.<sup>2</sup> The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at EDIS.<sup>3</sup> Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205-1810.

**SUPPLEMENTARY INFORMATION:** The Commission has received a complaint and a submission pursuant to section 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Rovi Corporation and Rovi Guides, Inc. on April 6, 2016. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain digital video receivers and hardware and software components thereof. The complaint names as respondents: Comcast Corporation, Philadelphia, PA; Comcast Cable Communications, LLC, Philadelphia, PA; Comcast Cable Communications Management, LLC, Philadelphia, PA; Comcast Business Communications, LLC, Philadelphia, PA; Comcast Holdings Corporation, Philadelphia, PA; Comcast Shared Services, LLC, Chicago, IL; Humax Co., Ltd., South Korea; Humax USA, Inc., Irvine, CA; Technicolor SA, France; Technicolor USA, Inc., Indianapolis, IN; Technicolor Connected Home USA LLC, Indianapolis, IN; Pace Ltd., England; Pace Americas, LLC, Boca Raton, FL; Arris International plc, Suwanee, GA; Arris Group Inc., Suwanee, GA; Arris Technology, Inc., Horsham, PA; Arris Enterprises Inc., Suwanee, GA; and Arris Solutions, Inc., Suwanee, GA. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or section 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive

conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

- (i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;
- (ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;
- (iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;
- (iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and
- (v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number ("Docket No. 3135") in a prominent place on the cover page and/or the first page. (*See Handbook for Electronic Filing Procedures, Electronic Filing Procedures*).<sup>4</sup> Persons with questions regarding filing should contact the Secretary (202-205-2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such

treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.<sup>5</sup>

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Dated: April 7, 2016.

**Lisa R. Barton,**

*Secretary to the Commission.*

[FR Doc. 2016-08356 Filed 4-11-16; 8:45 am]

**BILLING CODE 7020-02-P**

## INTERNATIONAL TRADE COMMISSION

[Investigation No. 731-TA-1269 (Final)]

### Silicomanganese From Australia

#### Determination

On the basis of the record<sup>1</sup> developed in the subject investigation, the United States International Trade Commission ("Commission") determines, pursuant to the Tariff Act of 1930 ("the Act"), that an industry in the United States is not materially injured or threatened with material injury, and the establishment of an industry in the United States is not materially retarded, by reason of imports of silicomanganese from Australia, provided for in subheading 7202.30.00 of the Harmonized Tariff Schedule of the United States, that have been found by the Department of Commerce ("Commerce") to be sold in the United States at less than fair value ("LTFV").

#### Background

The Commission, pursuant to section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)), instituted this investigation effective February 19, 2015, following receipt of a petition filed with the Commission and Commerce by Felman Production LLC, Letart, West Virginia. The Commission scheduled the final phase of the investigation following notification of a preliminary determination by Commerce that imports of silicomanganese from Australia were being sold at LTFV within the meaning of section 733(b) of the Act (19 U.S.C.

<sup>5</sup> Electronic Document Information System (EDIS): <http://edis.usitc.gov>.

<sup>1</sup> The record is defined in section 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

<sup>2</sup> United States International Trade Commission (USITC): <http://edis.usitc.gov>.

<sup>3</sup> Electronic Document Information System (EDIS): <http://edis.usitc.gov>.

<sup>4</sup> Handbook for Electronic Filing Procedures: [http://www.usitc.gov/secretary/fed\\_reg\\_notices/rules/handbook\\_on\\_electronic\\_filing.pdf](http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf).

1673b(b)). Notice of the scheduling of the final phase of the Commission's investigation and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of October 21, 2015 (80 FR 63833). The hearing was held in Washington, DC, on February 11, 2016, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made this determination pursuant to section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)). It completed and filed its determination in this investigation on April 6, 2016. The views of the Commission are contained in USITC Publication 4600 (April 2016), entitled *Silicomanganese from Australia: Investigation No. 731-TA-1269 (Final)*.

By order of the Commission.

Issued: April 6, 2016.

**Lisa R. Barton,**

*Secretary to the Commission.*

[FR Doc. 2016-08268 Filed 4-11-16; 8:45 am]

**BILLING CODE 7020-02-P**

## INTERNATIONAL TRADE COMMISSION

[Investigation No. 332-557]

### Aluminum: Competitive Conditions Affecting the U.S. Industry Institution of Investigation and Scheduling of Hearing

**AGENCY:** United States International Trade Commission.

**ACTION:** Notice of investigation and scheduling of a public hearing.

**SUMMARY:** Following receipt of a request dated February 24, 2016 from the U.S. House of Representatives, Committee on Ways and Means (Committee) under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)), the U.S. International Trade Commission (Commission) instituted investigation No. 332-557: *Aluminum: Competitive Conditions Affecting the U.S. Industry.*

**DATES:**

September 5, 2016: Deadline for filing requests to appear at the public hearing.

September 12, 2016: Deadline for filing pre-hearing briefs and statements.

September 29, 2016: Public hearing.

October 7, 2016: Deadline for filing post-hearing briefs and submissions.

February 21, 2017: Deadline for filing all other written statements.

June 26, 2017: Transmittal of Commission report to the Committee.

**ADDRESSES:** All Commission offices, including the Commission's hearing rooms, are located in the United States International Trade Commission Building, 500 E Street SW., Washington, DC. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov/edis3-internal/app>.

**FOR FURTHER INFORMATION CONTACT:**

Project Leader Karl Tsuji (202-205-3434 or [karl.tsuji@usitc.gov](mailto:karl.tsuji@usitc.gov)) for information specific to this investigation. For information on the legal aspects of these investigations, contact William Gearhart of the Commission's Office of the General Counsel (202-205-3091 or [william.gearhart@usitc.gov](mailto:william.gearhart@usitc.gov)). The media should contact Margaret O'Laughlin, Office of External Relations (202-205-1819 or [margaret.olaughlin@usitc.gov](mailto:margaret.olaughlin@usitc.gov)). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202-205-1810. General information concerning the Commission may also be obtained by accessing its Internet server (<http://www.usitc.gov>). Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202-205-2000.

**Background:** As requested by the Committee, the investigation will cover unwrought (e.g., primary and secondary) and wrought (e.g., semi-finished) aluminum products. The Commission's report will provide, to the extent that information is available:

- An overview of the aluminum industry in the United States and other major global producing and exporting countries, including production, production capacity, capacity utilization, employment, wages, inventories, supply chains, domestic demand, and exports;
- Information on recent trade trends and developments in the global market for aluminum, including U.S. and other major foreign producer imports and exports, and trade flows through third countries for further processing and subsequent exports;
- A comparison of the competitive strengths and weaknesses of aluminum production and exports in the United States and other major producing and exporting countries, including such factors as producer revenue and production costs, industry structure, input prices and availability, energy

costs and sources, production technology, product innovation, exchange rates, and pricing, as well as government policies and programs that directly or indirectly affect aluminum production and exporting in these countries;

- In countries where unwrought aluminum capacity has significantly increased, identify factors driving those capacity and related production changes; and

- A qualitative and, to the extent possible, quantitative assessment of the impact of government policies and programs in major foreign aluminum producing and exporting countries on their aluminum production, exports, consumption, and domestic prices, as well as on the U.S. aluminum industry and on aluminum markets worldwide. As requested, the report will focus primarily on the 2011-2015 time period, but examine longer term trends since 2001 when appropriate.

The Committee asked that the Commission transmit its report not later than 16 months after receipt of the request, and the Commission will transmit its report by June 26, 2017. The Committee also stated that it intends to make the Commission's report available to the public in its entirety and asked that the report not include any confidential business information.

**Public Hearing:** A public hearing in connection with this investigation will be held at the U.S. International Trade Commission Building, 500 E Street SW., Washington, DC, beginning at 9:30 a.m. on September 29, 2016. Requests to appear at the public hearing should be filed with the Secretary, no later than 5:15 p.m., September 5, 2016 in accordance with the requirements in the "Submissions" section below. All pre-hearing briefs and statements should be filed not later than 5:15 p.m., September 12, 2016; and all post-hearing briefs and statements should be filed not later than 5:15 p.m., October 7, 2016. In the event that, as of the close of business on September 5, 2016, no witnesses are scheduled to appear at the hearing, the hearing will be canceled. Any person interested in attending the hearing as an observer or nonparticipant should contact the Office of the Secretary at 202-205-2000 after September 5, 2016, for information concerning whether the hearing will be held.

**Written Submissions:** In lieu of or in addition to participating in the hearing, interested parties are invited to file written submissions concerning this investigation. All written submissions should be addressed to the Secretary, and should be received not later than

5:15 p.m., February 21, 2017. All written submissions must conform to the provisions of section 201.8 of the Commission's Rules of Practice and Procedure (19 CFR 201.8). Section 201.8 and the Commission's Handbook on Filing Procedures require that interested parties file documents electronically on or before the filing deadline and submit eight (8) true paper copies by 12:00 p.m. eastern time on the next business day. In the event that confidential treatment of a document is requested, interested parties must file, at the same time as the eight paper copies, at least four (4) additional true paper copies in which the confidential information must be deleted (see the following paragraphs for further information regarding confidential business information). Persons with questions regarding electronic filing should contact the Office of the Secretary, Docket Services Division (202-205-1802).

#### *Confidential Business Information.*

Any submissions that contain confidential business information must also conform to the requirements of section 201.6 of the Commission's Rules of Practice and Procedure (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the "confidential" or "non-confidential" version, and that the confidential business information is clearly identified by means of brackets. All written submissions, except for confidential business information, will be made available for inspection by interested parties.

As requested by the Committee, the Commission will not include any confidential business information in the report that it sends to the Committee or makes available to the public. However, all information, including confidential business information, submitted in this investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel for cybersecurity purposes. The Commission will not otherwise disclose any confidential business information in a manner that would reveal the operations of the firm supplying the information.

*Summaries of Written Submissions:* The Commission intends to publish

summaries of the positions of interested persons. Persons wishing to have a summary of their position included in the report should include a summary with their written submission. The summary may not exceed 500 words, should be in MS Word format or a format that can be easily converted to MS Word, and should not include any confidential business information. The summary will be published as provided if it meets these requirements and is germane to the subject matter of the investigation. The Commission will identify the name of the organization furnishing the summary and will include a link to the Commission's Electronic Document Information System (EDIS) where the full written submission can be found.

By order of the Commission.

Issued: April 6, 2016.

**Lisa Barton,**

*Secretary to the Commission.*

[FR Doc. 2016-08269 Filed 4-11-16; 8:45 am]

**BILLING CODE 7020-02-P**

## **LEGAL SERVICES CORPORATION**

### **Sunshine Act Meeting**

**SUMMARY:** Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, that the Operations and Regulations Committee (Committee) of the Board of Directors for the Legal Services Corporation (LSC) will hold a Rulemaking Workshop (Workshop) to solicit public input on revisions to LSC's Cost Standards and Procedures and the Property Acquisition and Management Manual (PAMM).

**DATE AND TIME:** Wednesday, April 20, 2016, 1:30-4:30 p.m. EDT.

**LOCATION:** F. William McCalpin Conference Center, Legal Services Corporation Headquarters, 3333 K Street NW., 3rd Floor, Washington DC 20007.

**PUBLIC OBSERVATION AND PARTICIPATION:** LSC encourages observation of and participation in the Workshop by interested individuals and organizations. The Workshop will be entirely open to public observation and will include opportunities for individuals who are not members of the panel to participate in person or via telephone. Persons interested in speaking during the public comment period are encouraged to pre-register by submitting a request in writing prior to close of business on Monday, April 18, 2016, to Stefanie K. Davis, Assistant General Counsel, at [sdavis@lsc.gov](mailto:sdavis@lsc.gov). Those who pre-register will be scheduled to speak first. LSC will

transcribe the meeting and make the transcript available to members of the public who are unable to attend. Individuals who wish to listen and/or participate in the proceedings remotely may do so by following the telephone call-in directions provided below.

#### **CALL-IN DIRECTIONS FOR PUBLIC OBSERVATION AND PARTICIPATION:**

- Call toll-free number: 1-872-240-3212;
- When prompted, enter the following numeric pass code: 925-917-349.

- When connected to the call, please immediately "MUTE" your telephone.

Members of the public are asked to keep their telephones muted to eliminate background noises. To avoid disrupting the meeting, please refrain from placing the call on hold if doing so will trigger recorded music or other sound. The Workshop moderator will solicit public comment as provided in the following Workshop Agenda.

**STATUS OF MEETING:** Open.

#### **MATTERS TO BE CONSIDERED:**

1. Introductory remarks.
  - Charles N.W. Keckler, Chair, Operations and Regulations Committee
2. Panelist introductions (including a description of the program's funding composition and brief overview of the areas in which each panelist sees the most differences between the requirements imposed by LSC and other funders).
  - Steve Pelletier, Northwest Justice Project
  - George Elliott, Legal Aid of Northwest Texas
  - Steve Ogilvie, Inland Counties Legal Services
  - AnnaMarie Johnson, Nevada Legal Services
  - Shamim Huq, Legal Aid Society of Northeastern New York
  - Patrick McClintock, Iowa Legal Aid Foundation
  - Jon Asher, Colorado Legal Services
  - Michael Maher, Legal Action of Wisconsin
  - Robin Murphy, National Legal Aid and Defender Association
3. Discussion of other funders' prior approval requirements for purchases of personal and real property.
4. Discussion of disposition of personal and real property acquired with non-LSC funds.
5. Discussion of approval requirements imposed by other funders for procurement of services.
6. Discussion of other funders' requirements governing intellectual property created using various funding sources.

7. Discussion of potential conflicts with other funders' requirements regarding leases of personal property.

8. Public comment.

9. Closing remarks.

• Charles N.W. Keckler, Chair, Operations and Regulations Committee

**CONTACT PERSON FOR INFORMATION:**

Stefanie Davis, Assistant General Counsel, at (202) 295-1563. Questions may be sent by electronic mail to [sdavis@lsc.gov](mailto:sdavis@lsc.gov).

**ACCESSIBILITY:** LSC complies with the Americans with Disabilities Act and Section 504 of the 1973 Rehabilitation Act. Upon request, meeting notices and materials will be made available in alternative formats to accommodate individuals with disabilities. Individuals who need other accommodations due to disability in order to attend the meeting in person or telephonically should contact Stefanie Davis, at (202) 295-1563 or [sdavis@lsc.gov](mailto:sdavis@lsc.gov), at least 2 business days in advance of the meeting. If a request is made without advance notice, LSC will make every effort to accommodate the request but cannot guarantee that all requests can be fulfilled.

Dated: April 8, 2016.

**Stefanie K. Davis,**

*Assistant General Counsel.*

[FR Doc. 2016-08498 Filed 4-8-16; 4:15 pm]

**BILLING CODE 7050-01-P**

## THE NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

### Institute of Museum and Library Services

#### Submission for OMB Review, Comment Request, Proposed Collection; Guidelines for Grants to States Program Five-Year Evaluations

**AGENCY:** Institute of Museum and Library Services, National Foundation on the Arts and the Humanities.

**ACTION:** Submission for OMB Review, Comment Request.

**SUMMARY:** The Institute of Museum and Library Service ("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. 3501 *et seq.*). 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. The purpose of this Notice is to solicit comments concerning the guidelines for the agency's Grants to States program's five-year evaluations.

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 CONTACT section below on or before May 10, 2016.

OMB is particularly interested in comments that help the agency to:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used;
- Enhance the quality, utility and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.* permitting electronic submissions of responses.

**ADDRESSES:** For a copy of the documents contact: Kim A. Miller, Management Analyst, Office of Impact Assessment and Learning, Institute of Museum and Library Services, 955 L'Enfant Plaza North SW., Suite 4000, Washington, DC 20024-2135. Ms. Miller can be reached by Telephone: 202-653-4762, Fax: 202-653-4601, or by email at [kmiller@imls.gov](mailto:kmiller@imls.gov) or by teletype (TTY/TDD) at 202-653-4614.

**SUPPLEMENTARY INFORMATION:** The Institute of Museum and Library Services (IMLS) is an independent Federal grant-making agency and is the primary source of federal support for the Nation's 123,000 libraries and 35,000 museums. IMLS provides a variety of grant programs to assist the Nation's museums and libraries in improving their operations and enhancing their services to the public. The IMLS Grants to States program is the largest source of federal funding support for library services in the United States. Using a population-based formula, more than

\$150 million is distributed among the State Library Administrative Agencies.

**Current actions:** This notice proposes clearance of the Guidelines for Grants to States Program Five-Year Evaluations. The 60-day notice for the Guidelines for Grants to States Program Five-Year Evaluations, was published in the **Federal Register** on January 20, 2016 (FR vol. 81, No. 12, pgs. 3165). The agency has taken into consideration the one comment that was received under this notice.

**Agency:** *Institute of Museum and Library Services.*

**Title:** *Guidelines for Grants to States Program Five-Year Evaluations.*

**OMB Number:** *To be determined.*

**Agency Number:** *3137.*

**Affected Public:** *State Library Administrative Agencies.*

**Number of Respondents:** *55.*

**Note:** *55 is the number of State Library Administrative Agencies that are responsible for the collection of this information and for reporting it to IMLS.*

**Frequency:** *Once every five years.*

**Burden hours per respondent:** *90.*

**Total burden hours:** *4,950.*

**Total Annualized capital/startup costs:** *\$138,303.*

**Total Annual Costs:** *N/A. Data collected every five years only.*

**Contact:** Comments should be sent to Office of Information and Regulatory Affairs, *Attn.:* OMB Desk Officer for Education, Office of Management and Budget, Room 10235, Washington, DC 20503, (202) 395-7316.

Dated: April 7, 2016.

**Kim A. Miller,**

*Management Analyst, Office of Impact Assessment and Learning.*

[FR Doc. 2016-08370 Filed 4-11-16; 8:45 am]

**BILLING CODE 7036-01-P**

## NUCLEAR REGULATORY COMMISSION

[NRC-2016-0073]

### Biweekly Notice; Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Biweekly notice.

**SUMMARY:** Pursuant to Section 189a.(2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular biweekly notice. The Act requires the Commission to publish notice of any amendments



issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued, from March 15, 2016, to March 28, 2016. The last biweekly notice was published on March 29, 2016.

**DATES:** Comments must be filed by May 12, 2016. A request for a hearing must be filed by June 13, 2016.

**ADDRESSES:** You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2016-0073. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; email: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov).

- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN-12-H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:** Lynn Ronewicz, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-1927, email: [Lynn.Ronewicz@nrc.gov](mailto:Lynn.Ronewicz@nrc.gov).

#### **SUPPLEMENTARY INFORMATION:**

### **I. Obtaining Information and Submitting Comments**

#### *A. Obtaining Information*

Please refer to Docket ID NRC-2016-0073 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2016-0073.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at

<http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section of this document.

- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

#### *B. Submitting Comments*

Please include Docket ID NRC-2016-0073, facility name, unit number(s), application date, and subject in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at <http://www.regulations.gov>, as well as entering the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

### **II. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination**

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in § 50.92 of title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; (2) create the possibility of a new or different kind

of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

#### *A. Opportunity To Request a Hearing and Petition for Leave To Intervene*

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the subject facility operating license or combined license. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Agency Rules of Practice and Procedure" in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located at One White Flint North, Room O1-F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at <http://www.nrc.gov/reading-rm/doc-collections/cfr/>. If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a

presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to

participate fully in the conduct of the hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with NRC regulations, policies and procedures.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii).

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of any amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by June 13, 2016. The petition must be filed in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document, and should meet the requirements for petitions for leave to intervene set forth in this section, except that under § 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. A State, local governmental body, Federally-

recognized Indian Tribe, or agency thereof may also have the opportunity to participate under 10 CFR 2.315(c).

If a hearing is granted, any person who does not wish, or is not qualified, to become a party to the proceeding may, in the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of position on the issues, but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission by June 13, 2016.

#### *B. Electronic Submissions (E-Filing)*

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at [hearing.docket@nrc.gov](mailto:hearing.docket@nrc.gov), or by telephone at 301-415-1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals/getting-started.html>. System requirements for accessing the E-Submittal server are detailed in the NRC's "Guidance for Electronic Submission," which is available on the agency's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>.

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they

can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the "Contact Us" link located on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>, by email to [MSHD.Resource@nrc.gov](mailto:MSHD.Resource@nrc.gov), or by a toll-free call at 1-866-672-7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at <http://ehd1.nrc.gov/ehd/>, unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, in some instances, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the

proceeding. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii).

For further details with respect to these license amendment applications, see the application for amendment which is available for public inspection in ADAMS and at the NRC's PDR. For additional direction on accessing information related to this document, see the "Obtaining Information and Submitting Comments" section of this document.

*Duke Energy Progress, Inc., Docket Nos. 50-325 and 50-324, Brunswick Steam Electric Plant (BSEP), Units 1 and 2, Brunswick County, North Carolina; Docket No. 50-261, H. B. Robinson Steam Electric Plant (RNP) Unit No. 2, Darlington County, South Carolina; and Docket No. 50-400, Shearon Harris Nuclear Power Plant (HNP), Unit 1, Wake and Chatham Counties, North Carolina*

*Date of amendment request:* February 1, 2016. A publicly-available version is in ADAMS under Accession No. ML16040A077.

*Description of amendment request:* The amendments would change the licensee's name from Duke Energy Progress, Inc. to Duke Energy Progress, LLC.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1 Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed changes do not involve a significant increase in the probability of any accident previously evaluated because no accident initiators or assumptions are affected. The proposed conversion and name change is administrative in nature and has no direct effect on any plant system, plant

personnel qualifications, or the operation and maintenance of BSEP, RNP, and HNP.

2. Does the proposed change create the possibility of a new or different kind of accident from any previously evaluated?

Response: No.

The proposed changes do not create the possibility of a new or different kind of accident from any previously evaluated because the proposed name change is administrative in nature and does not involve new failure mechanisms, malfunctions, or accident initiators. The proposed changes have no direct effect on any plant system, plant personnel qualifications, or operation and maintenance of BSEP, RNP, and HNP.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed changes will not involve a significant reduction in the margin of safety because the proposed changes do not involve changes to the initial conditions contributing to accident severity or consequences, or reduce response or mitigation capabilities. The proposed name change is administrative in nature and has no direct effect on any plant system, plant personnel qualifications, or operation and maintenance of BSEP, RNP, and HNP.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Lara S. Nichols, Deputy General Counsel, Duke Energy Corporation, 550 South Tryon St., M/C DEC45A, Charlotte, NC 28202.

*NRC Branch Chief:* Benjamin G. Beasley.

*Entergy Louisiana, LLC, and Entergy Operations, Inc., Docket No. 50-458, River Bend Station, Unit 1 (RBS), West Feliciana Parish, Louisiana*

*Date of amendment request:* October 29, 2015. A publicly-available version is in ADAMS under Accession No. ML15307A293.

*Description of amendment request:* The amendment proposes to modify Technical Specification (TS) 5.5.13, "Primary Containment Leakage Rate Testing Program," by incorporating Nuclear Energy Institute (NEI) topical report 94-01, Revision 3-A, as the implementation document for the RBS performance-based containment leakage rate testing program. Based on the guidance in NEI 94-01, Revision 3-A, the proposed change would allow the RBS Type A Test (Integrated Leak Rate Test) frequency to be extended from 10 to 15 years, and the Type C Tests (Local Leak Rate Tests) frequency to be extended from 60 to 75 months. Additionally, the amendment proposes

to modify Surveillance Requirement (SR) 3.6.5.1.3 to extend the frequency of the Drywell Bypass Test from 10 to 15 years and to revise its allowed extension per SR 3.0.2 from 12 to 9 months.

*Basis for proposed no significant hazards consideration determination:*

As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration. The NRC staff has reviewed the licensee's analysis against the standards of 10 CFR 50.92(c). The NRC staff's review is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed amendment incorporates NEI topical report 94-01, Revision 3-A, into TS 5.5.13 as the basis for the RBS containment leakage rate testing program, which would allow for extensions to the frequencies of the Type A and Type C Tests. The proposed amendment also requests an extension to the Drywell Bypass Test frequency. The proposed changes do not involve any physical changes to the plant or any changes in the normal operation or control of the plant. In its license amendment request, the licensee identified the loss-of-coolant accident (LOCA) inside containment and the fuel handling accident (FHA) as the previously evaluated accidents in the Updated Safety Analysis Report that could potentially be impacted by the change. Changing the frequency of containment leakage rate testing has no impact upon the likelihood of a LOCA or of an FHA. Therefore, the probability of occurrence of an accident previously evaluated is not significantly increased by the proposed amendment.

The guidelines in NEI 94-01, Revision 3-A, provide a framework for a licensee's containment leakage rate testing program, the purpose of which is to ensure that the primary containment limits the uncontrolled release of radioactivity to the environment during a design-basis accident. As part of its amendment request, the licensee evaluated the potential consequences of extending the test intervals and determined that the change in risk was estimated to be acceptably small and within the guidelines, as published in Regulatory Guide 1.174. The proposed amendment does not change the overall containment leakage rate limit specified by the TSs. Therefore, it is concluded that the proposed amendment does not significantly increase the consequences of an accident previously evaluated.

Based on the above discussion, the proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes do not involve any physical changes to the plant or any changes

in the normal operation or control of the plant. The proposed changes do not create any new accident precursors or initiators, and do not change any existing accident precursors or initiators, as described in the RBS safety analyses.

Therefore, the proposed amendment does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed amendment adopts the NRC-accepted guidelines of NEI 94-01, Revision 3-A, for the development of the RBS performance-based leakage rate testing program, to allow for frequency extensions for the Type A and Type C Tests. The proposed amendment also requests an extension to the Drywell Bypass Test frequency. The proposed changes do not alter the manner in which safety limits, limiting safety system setpoints, or limiting conditions for operation are determined. The specific requirements and conditions of the containment leakage rate testing program, as defined in the TSs, ensure that the primary containment will continue to provide a leaktight barrier to the uncontrolled release of radioactivity to the environment during a design-basis accident. The proposed amendment does not change the overall containment leakage rate limit specified by the TSs. Additionally, the proposed amendment does not include any changes to the Containment Inservice Inspection Plan at RBS, which serves to provide a high degree of assurance that the containment will not degrade in a manner that is not detectable by the Type A Test.

Based on the above discussion, the proposed amendment does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on its review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Joseph A. Aluise, Associate General Counsel—Nuclear, Entergy Services, Inc., 639 Loyola Avenue, New Orleans, LA 70113.

*NRC Branch Chief:* Meena K. Khanna.

*Entergy Nuclear Operations, Inc., Docket No. 50-293, Pilgrim Nuclear Power Station (PNPS), Plymouth County, Massachusetts*

*Date of amendment request:* January 14, 2016. A publicly available version is in ADAMS under Accession No. ML16021A459.

*Description of amendment request:* The amendment would revise the PNPS Emergency Plan to decrease the Emergency Response Organization (ERO) staff training requirements

identified for the “on-site” Chemistry Technician.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below, along with NRC edits in square brackets:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed training requirements change has no effect on normal plant operation or on any accident initiator. The change affects the response to radiological emergencies addressed in the SEP [site emergency plan]. The ability of the emergency response organization to respond adequately to radiological emergencies has been evaluated. Changes in the training provided to the on-shift organization, such as the reassignment of key on-shift emergency personnel to perform related RP [radiation protection] functions, provide assurance of an effective emergency response without competing or conflicting duties. An analysis was also performed on the effect of the proposed change on the timeliness of performing major tasks for the major functional areas of the SEP. The analysis concluded that the reduction in training requirements for the “on-shift” Chemistry Technician to support the initial RP support tasks does not affect the ability to perform the required RP Technician or Chemistry Technician tasks.

Therefore, the change in ERO staff training does not increase the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change affects the training requirements for the “on-shift” Chemistry Technician and for supplementing onsite personnel in response to a radiological emergency. It has been evaluated and determined not to significantly affect the ability to perform required or related functions. It has no effect on the plant design or on the normal operation of the plant and does not affect how the plant is physically operated under emergency conditions. The reduction in ERO training requirements for the “on shift” Chemistry Technician in the SEP does not affect the plant operating procedures which are performed by plant staff during all plant conditions.

No new or different accidents are postulated to occur and there are no changes in any of the accidents previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change does not affect plant design or method of operation. 10 CFR 50.47(b) and 10 CFR 50 Appendix E establish emergency planning standards and

requirements that require adequate staffing, satisfactory performance of key functional areas and critical tasks, and timely augmentation of the response capability. Since the SEP was originally developed, there have been improvements in the technology used to support the SEP functions and in the capabilities of onsite personnel. A functional analysis was performed on the effect of the proposed change on the timeliness of performing major tasks for the functional areas of the SEP. The analysis concluded that a reduction in training requirements for the “on-shift” Chemistry Technician would not significantly affect the ability to perform the required SEP tasks. Thus, the proposed change has been determined not to adversely affect the ability to meet the emergency planning standards as described in 10 CFR 50.47(b) and requirements in 10 CFR 50 Appendix E.

The proposed ERO staff training change does not involve a reduction in any margin of safety. The proposed change is consistent with the original and current ERO staffing levels implemented at PNPS.

The NRC staff has reviewed the licensee’s analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Ms. Jeanne Cho, Assistant General Counsel, Entergy Nuclear Operations, Inc., 440 Hamilton Avenue, White Plains, NY 10601.

*NRC Branch Chief:* Travis L. Tate.

*Exelon Generation Company, LLC, Docket Nos. 50–317 and 50–318, Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2, Calvert County, Maryland*

*Date of amendment request:* February 4, 2016. A publicly available version is in ADAMS under Accession No. ML16035A227.

*Description of amendment request:* The amendments would add Surveillance Requirement (SR) 3.5.2.10 to the list of applicable SRs shown in SR 3.5.3.1.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below with NRC staff corrections shown in [brackets]:

1. Does the proposed amendment involve a significant increase in the probability or consequences of any accident previously evaluated?

Response: No.

The proposed LAR [license amendment request] is purely an administrative change; therefore, the probability of any accident previously evaluated is not significantly increased. The systems and components required by the TS [technical specifications]

for which SR 3.5.2.10 is applicable, continue to be operable and capable of performing any mitigation function assumed in the accident analysis. As a result, the consequences of any accident previously evaluated are not significantly increased.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an[y] accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any [accident] previously evaluated?

Response: No.

The proposed LAR is purely an administrative change. The proposed change to add SR 3.5.2.10 to the list of applicable surveillances in SR 3.5.3.1 does not create a new or different kind of accident [than] previously evaluated.

The change does not involve a physical alteration of the plant (*i.e.*, no new or different type of equipment will be installed) or a change in the methods governing normal plant operation. In addition, the change does not impose any new or different requirements. The change does not alter assumptions made in the safety analysis. The proposed change is consistent with the safety analysis assumptions and current plant operating practice.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed LAR is purely an administrative change to add SR 3.5.2.10 to the list of applicable surveillances in SR 3.5.3.1.

The design, operation, testing methods, and acceptance criteria for systems, structures, and components (SSCs), specified in applicable codes and standards (or alternatives approved for use by the NRC) will continue to be met as described in the plant licensing basis (including the Final Safety Analysis Report and Bases to TS). Similarly, there is no impact to safety analysis acceptance criteria as described in the plant licensing basis.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee’s analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Tamra Domeyer, Associate General Counsel, Exelon Generation Company, LLC, 4300 Winfield Rd., Warrenville, IL 60555.

*NRC Branch Chief:* Travis L. Tate.

*Exelon Generation Company, LLC (EGC), Docket No. 50-461, Clinton Power Station (CPS), Unit No. 1, DeWitt County, Illinois*

*Date of amendment request:* January 29, 2016. A publicly-available version is in ADAMS under Accession No. ML16029A418.

*Description of amendment request:* The amendment would revise the post-loss-of-coolant-accident (post-LOCA) drawdown time for secondary containment from 12 to 19 minutes as described in the CPS Updated Safety Analysis Report and technical specification bases.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change results in additional heat added to Secondary Containment and the resultant increase in the time to achieve and maintain the required negative pressure in Secondary Containment following a LOCA. Neither the additional heat load from DCS [dry-cask storage] activities, nor the resultant increase in the time to achieve and maintain the required negative pressure in Secondary Containment affect any initiator or precursor of any accident previously evaluated. Therefore, the proposed change does not involve a significant increase in the probability of an accident previously evaluated.

The proposed change results in an increase in the post-LOCA radiological dose to a Control Room occupant. However, the resultant post-LOCA Control Room dose remains within the regulatory limits of 10 CFR 50.67 and GDC [General Design Criterion] 19. Therefore, the proposed change does not involve a significant increase in the consequences of an accident previously evaluated.

In summary, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change does not alter the design function or operation of Secondary Containment or the Standby Gas Treatment system [SGTS], or the ability of each to perform its design function. EGC has evaluated the post-LOCA pressure response of Secondary Containment assuming the higher heat load, utilizing the design basis short-term pressure response analysis. The results of this analysis validated that SGTS will achieve and maintain the required

negative pressure in Secondary Containment within the specified timeframe. The proposed change does not alter the safety limits, or safety analysis associated with the operation of the plant. Accordingly, the change does not introduce any new accident initiators. Rather, this proposed change is the result of an evaluation of the Control Room doses following the most limiting LOCA that can occur at CPS. The proposed change does not introduce any new modes of plant operation. As a result, no new failure modes are introduced.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The revised post-LOCA dose consequences to a Control Room occupant were calculated in accordance with the requirements of 10 CFR 50.67, Regulatory Guide 1.183, and SRP [Standard Review Plan] 15.0.1 and are consistent with the post-LOCA dose calculations approved by the NRC in Amendment No. 167 to the CPS Facility Operating License NPF-62.

The margin of safety is considered to be that provided by meeting the applicable regulatory limits. The additional heat load that is added to Secondary Containment during DCS activities, leading to an increase in Secondary Containment drawdown time results in an increase in Control Room dose following the LOCA design basis accident. However, since the Control Room dose following the design basis accident remains within the regulatory limits, there is not a significant reduction in a margin of safety.

Therefore, operation of CPS in accordance with the proposed change will not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Bradley J. Fewell, Associate General Counsel, Exelon Nuclear, 4300 Winfield Road, Warrenville, IL 60555.

*Acting NRC Branch Chief:* Justin C. Poole.

*FirstEnergy Nuclear Operating Company (FENOC), et al., Docket No. 50-346, Davis-Besse Nuclear Power Station (DBNPS), Unit No. 1, Ottawa County, Ohio*

*Date of amendment request:* December 16, 2015, as supplemented by letters dated February 2 and March 7, 2016. Publicly-available versions are in ADAMS under Accession Nos. ML15350A314, ML16033A085, and ML16067A195.

*Description of amendment request:* The amendment would allow the

licensee to transition the current fire protection program at DBNPS to a performance-based, risk-informed fire protection program consistent with 10 CFR, Section 50.48(c), "National Fire Protection Association Standard NFPA 805." The 2001 Edition of NFPA 805, "Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants," is incorporated by reference into 10 CFR 50.48(c), with exceptions, modifications, and supplementation. The amendment would also allow the licensee to make changes to the DBNPS fire protection program without prior NRC approval, provided that specified conditions are met. The proposed amendment would change the facility operating license, technical specifications, and design basis.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

Operation of DBNPS in accordance with the proposed amendment does not increase the probability or consequences of accidents previously evaluated. The Updated Final Safety Analysis Report (UFSAR) documents the analyses of design basis accidents (DBAs) at DBNPS. The proposed amendment does not affect accident initiators, nor does it alter design assumptions, conditions, or configurations of the facility that would increase the probability of accidents previously evaluated. Further, the changes to be made for fire hazard protection and mitigation do not adversely affect the ability of SSCs [structures, systems, and components] to perform their design functions for accident mitigation, nor do they affect the postulated initiators or assumed failure modes for accidents described and evaluated in the UFSAR. SSCs required to shut down the reactor safely and to maintain it in a safe and stable condition will remain capable of performing their design functions.

The purpose of the proposed amendment is to permit DBNPS to adopt a new fire protection licensing basis, which complies with the requirements of 10 CFR 50.48(a) and 10 CFR 50.48(c) and the guidance in [Regulatory Guide] RG 1.205, Revision 1. The NRC considers that NFPA 805 provides an acceptable methodology and performance criteria for licensees to identify fire protection requirements that are an acceptable alternative to the 10 CFR 50, Appendix R required fire protection features (69 FR 33536, June 16, 2004). Engineering analyses, which may include engineering evaluations, probabilistic safety assessments, and fire modeling calculations, have been performed to demonstrate that the

performance-based requirements of NFPA 805 have been satisfied.

NFPA 805, taken as a whole, provides an acceptable alternative for satisfying General Design Criterion 3 (GDC 3) of Appendix A to 10 CFR 50, meets the underlying intent of the NRC's existing fire protection regulations and guidance, and provides for DID [defense-in-depth]. The goals, performance objectives, and performance criteria specified in Chapter 1 of the standard ensure that, if there are any increases in CDF [core damage frequency] or risk, the increase will be small and consistent with the intent of the Commission's Safety Goal Policy.

Based on this, the implementation of the proposed amendment does not increase the probability of any accident previously evaluated. Equipment required to mitigate an accident remains capable of performing the assumed function(s). The proposed amendment will not affect the source term, containment isolation, or radiological release assumptions used in evaluating the radiological consequences of any accident previously evaluated. The applicable radiological dose criteria will continue to be met. Therefore, the consequences of any accident previously evaluated are not significantly increased with the implementation of the proposed amendment.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

Operation of DBNPS in accordance with the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated. The proposed change does not alter the requirements or functions for systems required during accident conditions. Implementation of the new fire protection licensing basis that complies with the requirements of 10 CFR 50.48(a) and 10 CFR 50.58(c) and the guidance in RG 1.205, Revision 1, will not result in new or different accidents.

The proposed amendment does not adversely affect accident initiators or alter design assumptions, conditions, or configurations of the facility. The proposed amendment does not adversely affect the ability of SSCs to perform their design function. SSCs required to maintain the plant in a safe and stable condition remain capable of performing their design functions.

The proposed amendment does not introduce new or different accident initiators, nor does it alter design assumptions, conditions, or configurations of the facility. The proposed amendment does not adversely affect the ability of SSCs to perform their design function. SSCs required to safely shutdown the reactor and maintain it in a safe and stable condition remain capable of performing their design functions.

The purpose of the proposed amendment is to permit DBNPS to adopt a new fire protection licensing basis that complies with the requirements of 10 CFR 50.48(a) and 10 CFR 50.48(c) and the guidance in Regulatory Guide 1.205, Revision 1. The NRC considers that NFPA 805 provides an acceptable methodology and appropriate performance

criteria for licensees to identify fire protection systems and features that are an acceptable alternative to the 10 CFR 50, Appendix R required fire protection features (69 FR [Federal Register] 33536, June 16, 2004).

The requirements of NFPA 805 address only fire protection and the impacts of fire on the plant that have previously been evaluated. Based on this, implementation of the proposed amendment would not create the possibility of a new or different kind of accident from any kind of accident previously evaluated. No new accident scenarios, transient precursors, failure mechanisms, or limiting single failures will be introduced as a result of this amendment. There will be no adverse effect or challenges imposed on any safety-related system as a result of this amendment. Therefore, the possibility of a new or different kind of accident from any kind of accident previously evaluated is not created with the implementation of this amendment.

3. Does the proposed amendment involve a significant reduction in a margin of safety? Response: No.

Operation of DBNPS in accordance with the proposed amendment does not involve a significant reduction in the margin of safety. The proposed amendment does not alter the manner in that safety limits, limiting safety system settings or limiting conditions for operation are determined. The safety analysis acceptance criteria are not affected by this change. The proposed amendment does not adversely affect existing plant safety margins or the reliability of equipment assumed to mitigate accidents in the UFSAR. The proposed amendment does not adversely affect the ability of SSCs to perform their design function. SSCs required to safely shut down the reactor and to maintain it in a safe and stable condition remain capable of performing their design functions.

The purpose of the proposed amendment is to permit FENOC to adopt a new fire protection licensing basis which complies with the requirements in 10 CFR 50.48(a) and 10 CFR 50.48(c) and the guidance in RG 1.205, Revision 1. The NRC considers that NFPA 805 provides an acceptable methodology and performance criteria for licensees to identify fire protection systems and features that are an acceptable alternative to the 10 CFR 50 Appendix R required fire protection features (69 FR 33536, June 16, 2004). Engineering analyses, which may include engineering evaluations, probabilistic safety assessments, and fire modeling calculations, have been performed to demonstrate that the performance-based requirements of NFPA 805 do not result in a significant reduction in the margin of safety.

The proposed changes are evaluated to ensure that risk and safety margins are kept within acceptable limits. Therefore, the transition to NFPA 805 does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff

proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* David W. Jenkins, Attorney, FirstEnergy Corporation, Mail Stop A-GO-15, 76 South Main Street, Akron, OH 44308.  
*Acting NRC Branch Chief:* Justin C. Poole.

*Nebraska Public Power District, Docket No. 50-298, Cooper Nuclear Station, Nemaha County, Nebraska*

*Date of amendment request:* March 11, 2016. A publicly-available version is in ADAMS under Accession No. ML16076A433.

*Description of amendment request:* The amendment would adopt Technical Specification (TS) Task Force (TSTF) Change Traveler TSTF-535, Revision 0, "Revise Shutdown Margin [SDM] Definition to Address Advanced Fuel Designs." The SDM (*i.e.*, the amount of reactivity by which the reactor is subcritical), is calculated under the conservative conditions that the reactor is Xenon free, the most reactive control rod is outside the reactor core, and the moderator temperature produces the maximum reactivity. For standard fuel designs, maximum reactivity occurs at a moderator temperature of 68 degrees Fahrenheit (°F), which is reflected in the temperature specified in the TSs. New, advanced boiling water reactor fuel designs can have a higher reactivity at moderator shutdown temperatures above 68 °F. Therefore, the proposed amendment, consistent with TSTF-535, Revision 0, seeks to modify the TSs to require the SDM to be calculated at whatever temperature produces the maximum reactivity (*i.e.*, temperatures at or above 68 °F). The availability of this TS improvement was announced in the **Federal Register** (FR) published on February 26, 2013 (78 FR 13100), as part of the Consolidated Line Item Improvement Process, and has been requested with no variations or deviations.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change revises the definition of SDM. SDM is not an initiator to any accident previously evaluated. Accordingly, the proposed change to the definition of SDM has no effect on the probability of any

accident previously evaluated. SDM is an assumption in the analysis of some previously evaluated accidents and inadequate SDM could lead to an increase in consequences for those accidents. However, the proposed change revises the SDM definition to ensure that the correct SDM is determined for all fuel types at all times during the fuel cycle. As a result, the proposed change does not adversely affect the consequences of any accident previously evaluated.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change revises the definition of SDM. The change does not involve a physical alteration of the plant (*i.e.*, no new or different type of equipment will be installed) or a change in the methods governing normal plant operations. The change does not alter assumptions made in the safety analysis regarding SDM.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change revises the definition of SDM. The proposed change does not alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation are determined. The proposed change ensures that the SDM assumed in determining safety limits, limiting safety system settings or limiting conditions for operation is correct for all Boiling Water Reactor fuel types at all times during the fuel cycle.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Mr. John C. McClure, Nebraska Public Power District, P.O. Box 499, Columbus, NE 68602-0499.

*NRC Branch Chief:* Meena K. Khanna.

*South Carolina Electric & Gas Company, South Carolina Public Service Authority, Docket No. 50-395, Virgil C. Summer Nuclear Station, Unit 1, Fairfield County, South Carolina*

*Date of amendment request:*

December 16, 2015, as supplemented by letter dated March 7, 2016. Publicly-available versions are in ADAMS under

Accession Nos. ML15356A048 and ML16069A021, respectively.

*Description of amendment request:* The licensee proposes to revise TS 3/4.3.1, "Reactor Trip System Instrumentation," and TS 3/4.3.2, "Engineered Safety Feature Actuation System Instrumentation," to implement the Allowed Outage Time, Bypass Test Time, and Surveillance Frequency changes approved by the NRC in WCAP-15376-P-A, Rev. 1, "Risk-Informed Assessment of the Reactor Trip System (RTS) and Engineered Safety Features Actuation System (ESFAS) Surveillance Test Intervals and Reactor Trip Breaker Test and Completion Times."

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The overall protection system performance will remain within the bounds of the previously performed accident analyses since no hardware changes are proposed. The same reactor trip system (RTS) and engineered safety feature actuation system (ESFAS) instrumentation will continue to be used. The protection systems will continue to function in a manner consistent with the plant design basis. These changes to the Technical Specifications do not result in a condition where the design, material, and construction standards that were applicable prior to the change are altered.

The proposed changes will not modify any system interfaces. The proposed changes will not affect the probability of any event initiators. There will be no degradation in the performance of or an increase in the number of challenges imposed on safety-related equipment assumed to function during an accident situation. There will be no change to normal plant operating parameters or accident mitigation performance. The proposed changes will not alter any assumptions or change any mitigation actions in the radiological consequence evaluations in the Final Safety Analysis Report (FSAR).

The determination that the results of the proposed changes are acceptable was established in the NRC Safety Evaluation prepared for WCAP-1 5376-P-A (issued by letter dated December 20, 2002 [ML023540534]). Implementation of the proposed changes will result in an insignificant risk impact. Applicability of these conclusions has been verified through plant-specific reviews and implementation of the generic analysis results in accordance with the NRC Safety Evaluation conditions.

The proposed changes to the Completion Times, bypass test times, and Surveillance Frequencies reduce the potential for

inadvertent reactor trips and spurious engineered safety feature (ESF) actuations, and therefore do not increase the probability of any accident previously evaluated. The proposed changes do not change the response of the plant to any accidents and have an insignificant impact on the reliability of the RTS and ESFAS signals. The RTS and ESFAS instrumentation will remain highly reliable and the proposed changes will not result in a significant increase in the risk of plant operation. This is demonstrated by showing that the impact on plant safety as measured by the increase in core damage frequency (CDF) is less than  $1.0E-06$  per year and the increase in large early release frequency (LERF) is less than  $1.0E-07$  per year. In addition, for the Completion Time changes, the incremental conditional core damage probabilities (ICCDP) and incremental conditional large early release probabilities (ICLERP) are less than  $5.0E-07$  and  $5.0E-08$ , respectively. These changes meet the acceptance criteria in Regulatory Guides 1.174 and 1.177. Therefore, since the RTS and ESFAS instrumentation will continue to perform their functions with high reliability as originally assumed, and the risk impact as measured by the  $\Delta$ CDF,  $\Delta$ LERF, ICCDP, and ICLERP risk metrics is within the acceptance criteria of existing regulatory guidance, there will not be a significant increase in the consequences of any accidents.

The proposed changes do not adversely affect accident initiators or precursors nor alter the design assumptions, conditions, or configuration of the facility or the manner in which the plant is operated and maintained. The proposed changes do not alter or prevent the ability of structures, systems, and components (SSCs) from performing their intended function to mitigate the consequences of an initiating event within the assumed acceptance limits. The proposed changes do not affect the source term, containment isolation, or radiological release assumptions used in evaluating the radiological consequences of an accident previously evaluated. The proposed changes are consistent with safety analysis assumptions and resultant consequences.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

There are no hardware changes nor are there any changes in the method by which any safety-related plant system performs its safety function. The proposed changes will not affect the normal method of plant operation. No performance requirements will be affected or eliminated.

The proposed changes will not result in physical alteration to any plant system nor will there be any change in the method by which any safety-related plant system performs its safety function. The proposed changes do not include any changes to the instrumentation setpoints or changes to the accident analysis assumptions.

No new accident scenarios, transient precursors, failure mechanisms, or limiting



single failures are introduced as a result of these changes. There will be no adverse effect or challenges imposed on any safety-related system as a result of these changes.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?  
Response: No.

The proposed changes do not affect the acceptance criteria for any analyzed event nor is there a change to any Safety Analysis Limit (SAL). There will be no effect on the manner in which safety limits, limiting safety system settings, or limiting conditions for operation are determined nor will there be any effect on those plant systems necessary to assure the accomplishment of protection functions.

The redundancy of RTS and ESFAS is maintained, and diversity with regard to the signals that provide reactor trip and ESF actuation is also maintained. All signals credited as primary or secondary, and all operator actions credited in the accident analyses will remain the same. The proposed changes will not result in plant operation in a configuration outside the design basis. The calculated impact on risk is insignificant and meets the acceptance criteria contained in Regulatory Guides 1.174 and 1.177. Although there was no attempt to quantify any positive human factors benefit due to increased Completion Times and bypass test times, it is expected that there would be a net benefit due to a reduced potential for spurious reactor trips and actuations associated with testing.

Implementation of the proposed changes is expected to result in an overall improvement in safety, as follows:

(a) Reduced testing should result in fewer inadvertent reactor trips, less frequent actuation of ESFAS components, less frequent distraction of operations personnel without significantly affecting RTS and ESFAS reliability.

(b) The Completion Time extensions for the reactor trip breakers should provide additional time to complete test and maintenance activities while at power, potentially reducing the number of forced outages related to compliance with reactor trip breaker Completion Times, and provide consistency with the Completion Times for the logic trains.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* J. Hagood Hamilton, Jr., South Carolina Electric & Gas Company, P.O. Box 764, Columbia, SC 29218.

*NRC Branch Chief:* Michael T. Markley.

*Southern Nuclear Operating Company, Inc., Docket Nos. 52-025 and 52-026, Vogtle Electric Generating Plant (VEGP), Units 3 and 4, Burke County, Georgia*

*Date of amendment request:* February 15, 2016. A publicly-available version is in ADAMS under Accession No. ML16046A009.

*Description of amendment request:* The proposed change would amend Combined License Nos. NPF-91 and NPF-92 for the VEGP Units 3 and 4. The requested amendment proposes changes to the Updated Final Safety Analysis Report (UFSAR) in the form of departures from the incorporated plant-specific Design Control Document Tier 2 information and involves related changes to the associated plant-specific Tier 2\* information. Specifically, the proposed departures consist of changes to UFSAR text and tables, and information incorporated by reference into the UFSAR related to updates to WCAP-16096, "Software Program Manual for Common Q™ Systems," and WCAP-16097, "Common Qualified Platform Topical Report."

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

WCAP-16096 (Common Q Software Program Manual) was updated to Revision 4 to reference later NRC endorsed regulatory guides and standards and update the requirements for the software design and development processes for the Common Q portion of the AP1000 Protection and Safety Monitoring System (PMS). WCAP-16097 (Common Q Topical Report) was updated to Revision 3 to describe new Common Q components and standards currently used for the AP1000 PMS implementation of the Common Q platform. These two WCAPs have been reviewed and approved by the NRC in Safety Evaluations dated February 7, 2013. WCAP-15927 was updated to reference the newest revisions of WCAP-16096 and WCAP-16097 and for editorial corrections. The proposed activity adopts the updated versions as incorporated by reference documents into the UFSAR. Other proposed document changes support the implementation of the updated versions of WCAP-16096, WCAP-16097, and WCAP-15927.

The Common Q platform is an acceptable platform for nuclear safety-related applications. The Common Q system meets the requirements of 10 CFR part 50, Appendix A, General Design Criteria (Criteria 1, 2, 4, 13, 19, 20, 21, 22, 23, 24, and 25),

the Institute of Electrical and Electronics Engineers Standard 603-1991 for the design of safety-related reactor protection systems, engineered safety features systems and other plant systems, and the guidelines of Regulatory Guide 1.152 and supporting industry standards for the design of digital systems.

Because the Common Q platform and the PMS implementation of the Common Q platform meet the criteria in the applicable General Design Criteria, the revisions to these documents do not affect the prevention and mitigation of abnormal events, such as accidents, anticipated operational occurrences, earthquakes, floods and turbine missiles, or their safety or design analyses as described in the licensing basis. The incorporation of the updated documents does not adversely affect the interface with any structure, system, or component accident initiator or initiating sequence of events. Thus, the probabilities of the accidents previously evaluated in the UFSAR are not affected.

Therefore, the proposed amendment does not involve an increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes to adopt the updated WCAP-16096, WCAP-16097, and WCAP-15927 into the UFSAR do not adversely affect the design or operation of safety-related equipment or equipment whose failure could initiate an accident beyond what is already described in the licensing basis. These changes do not adversely affect fission product barriers. No safety analysis or design basis acceptance limit/criterion is challenged or exceeded by the requested change.

Therefore, this activity does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed changes to adopt the updated WCAP-16096, WCAP-16097, and WCAP-15927 into the UFSAR do not adversely affect the design, construction, or operation of any plant SSCs, including any equipment whose failure could initiate an accident or a failure of a fission product barrier. No analysis is adversely affected by the proposed changes. Furthermore, no system function, design function, or equipment qualification will be adversely affected by the changes.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Mr. M. Stanford Blanton, Balch & Bingham LLP, 1710 Sixth Avenue North, Birmingham, AL 35203–2015.

*Acting NRC Branch Chief:* John McKirgan.

*Tennessee Valley Authority (TVA), Docket Nos. 50–327 and 50–328, Sequoyah Nuclear Plant, Units 1 and 2, Hamilton County, Tennessee*

*Date of amendment request:* March 11, 2016. A publicly-available version is in ADAMS under Accession No. ML16071A333.

*Description of amendment request:* The amendments would revise the Technical Specifications to add a new condition to extend the allowed completion time to restore one Essential Raw Cooling Water train to OPERABLE status from 72 hours to 7 days for planned maintenance, when the opposite unit is defueled or in Mode 6, following defueling under certain restrictions.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below.

1. Does the proposed amendment involve a significant increase in the probability or consequence of an accident previously evaluated?

Response: No.

The proposed change adds new Condition A to Technical Specification (TS) 3.7.8, Essential Raw Cooling Water (ERCW) System for Sequoyah Nuclear Plant (SQN) Units 1 and 2. The proposed change will extend the allowed completion time to restore ERCW System train to OPERABLE status from 72 hours to 7 days for planned maintenance when the opposite unit is defueled or in mode 6 following defueled with refueling water cavity level  $\geq$  [greater than or equal to] 23 ft. above top of reactor vessel flange and UHS [ultimate heat sink] Temperature is  $\leq$  [less than or equal to] 79 degrees F. This change does not result in any physical changes to plant safety-related structures, systems, or components (SSCs). The UHS and associated ERCW system function is to remove plant system heat loads during normal and accident conditions. As such, the UHS and ERCW system are not design basis accident initiators, but instead perform accident mitigation functions by serving as the heat sink for safety-related equipment to ensure the conditions and assumptions credited in the accident analyses are preserved. During operation under the proposed change with one ERCW train inoperable, the other ERCW train will continue to perform the design function of the ERCW system. Therefore, the proposed change does not involve a significant increase in the probability of an accident previously evaluated.

Accordingly, as demonstrated by TVA design heat transfer and flow modeling calculations, operation with one ERCW System inoperable for 7 days for planned maintenance when the opposite unit is defueled or in mode 6 following defueled with refueling water cavity level  $\geq$  23 ft. above top of reactor vessel flange, the fuel cladding, Reactor Coolant System (RCS) pressure boundary, and containment integrity limits are not challenged during worst-case post-accident conditions. Accordingly, the conclusions of the accident analyses will remain as previously evaluated such that there will be no significant increase in the post-accident dose consequences.

Therefore, the proposed change does not involve a significant increase in the probability or consequence of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change does not involve any physical changes to plant safety related SSCs or alter the modes of plant operation in a manner that is outside the bounds of the current UHS and ERCW system design heat transfer and flow modeling analyses. The proposed change to add new Condition A to TS 3.7.8, ERCW System, which would extend the allowed completion time to restore ERCW System train to OPERABLE status from 72 hours to 7 days for planned maintenance when the opposite unit is defueled or in mode 6 following defueled with refueling water cavity level  $\geq$  23 ft. above top of reactor vessel flange. Thus, although the specified ERCW system alignments result in reduced heat transfer flow capability, the plant's overall ability to reject heat to the UHS during normal operation, normal shutdown, and hypothetical worst-case accident conditions will not be significantly affected by this proposed change. Because the safety and design requirements continue to be met and the integrity of the RCS pressure boundary is not challenged, no new credible failure mechanisms, malfunctions, or accident initiators are created, and there will be no effect on the accident mitigating systems in a manner that would significantly degrade the plant's response to an accident.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed change to add new Condition A to TS 3.7.8, ERCW System, which would extend the allowed completion time to restore ERCW System train to OPERABLE status from 72 hours to 7 days for planned maintenance when the opposite unit is defueled or in mode 6 following defueled with refueling water cavity level  $\geq$  23 ft. above top of reactor vessel flange. As demonstrated by TVA design basis heat transfer and flow modeling calculations, the design limits for fuel cladding, RCS pressure boundary, and containment integrity are not exceeded under both normal and post-

accident conditions. As required, these calculations include evaluation of the worst-case combination of meteorology and operational parameters, and establish adequate margins to account for measurement and instrument uncertainties. While operating margins have been reduced by the proposed change in order to support necessary maintenance activities, the current limiting design basis accidents remain applicable and the analyses conclusions remain bounding such that the accident safety margins are maintained. Accordingly, the proposed change will not significantly degrade the margin of safety of any SSCs that rely on the UHS and ERCW system for heat removal to perform their safety related functions.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, 6A West Tower, Knoxville, TN 37902.

*NRC Branch Chief:* Benjamin G. Beasley.

*Wolf Creek Nuclear Operating Corporation, Docket No. 50–482, Wolf Creek Generating Station, Coffey County, Kansas*

*Date of amendment request:* January 27, 2016. A publicly-available version is in ADAMS under Accession No. ML16033A470.

*Description of amendment request:* The amendment would revise the Technical Specifications to allow the use of Optimized ZIRLO™ as an approved fuel rod cladding.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change would allow the use of Optimized ZIRLO™ clad nuclear fuel in the reactor. The NRC approved topical report WCAP–12610–P–A & CENPD–404–P–A, Addendum 1–A, addresses Optimized ZIRLO™ and demonstrates that Optimized ZIRLO™ has essentially the same properties as currently licensed ZIRLO®. The fuel cladding itself is not an accident initiator and does not affect accident probability. Use of Optimized ZIRLO™ fuel cladding will

continue to meet the 10 CFR 50.46 acceptance criteria and, therefore, will not increase the consequences of an accident.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

Use of Optimized ZIRLO™ clad fuel will not result in changes in the operation or configuration of the facility. Topical Report WCAP-12610-P-A & CENPD-404-P-A, Addendum 1-A, demonstrated that the material properties of Optimized ZIRLO™ are similar to those of standard ZIRLO®. Therefore, Optimized ZIRLO™ fuel rod cladding will perform similarly to those fabricated from standard ZIRLO®, thus precluding the possibility of the fuel cladding becoming an accident initiator and causing a new or different type of accident.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change will not involve a significant reduction in the margin of safety because it has been demonstrated that the material properties of the Optimized ZIRLO™ are not significantly different from those of standard ZIRLO®. Optimized ZIRLO™ is expected to perform similarly to standard ZIRLO® for all normal operating and accident scenarios, including both loss-of-coolant accident (LOCA) and non-LOCA scenarios. For LOCA scenarios, where the slight difference in Optimized ZIRLO™ material properties relative to standard ZIRLO® could have some impact on the overall accident scenario, plant-specific LOCA analyses using Optimized ZIRLO™ properties will demonstrate that the acceptance criteria of 10 CFR 50.46 have been satisfied.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Jay Silberg, Esq., Pillsbury Winthrop Shaw Pittman LLP, 2300 N Street NW., Washington, DC 20037.

*NRC Branch Chief:* Robert J. Pascarelli.

### III. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last biweekly notice, the

Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items can be accessed as described in the "Obtaining Information and Submitting Comments" section of this document.

*Duke Energy Carolinas, LLC, Docket Nos. 50-369 and 50-370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina*

*Date of amendment request:* June 30, 2015, as supplemented by letters dated August 11, 2015; September 24, 2015; October 8, 2015; December 7, 2015; February 10, 2016; and February 25, 2016.

*Brief description of amendments:* The amendments revised selected Technical Specification Completion Times to support repair activity associated with the Nuclear Service Water System, Train 'A'.

*Date of issuance:* March 16, 2016.

*Effective date:* As of the date of issuance and shall be implemented within 30 days of issuance.

*Amendment Nos.:* 282 and 261. A publicly-available version is in ADAMS

under Accession No. ML15306A141; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

*Facility Operating License Nos. NPF-9 and NPF-18:* Amendments revised the Facility Operating Licenses and Technical Specifications.

*Date of initial notice in Federal Register:* August 20, 2015 (80 FR 50663). The supplemental letters dated August 11, 2015; September 24, 2015; October 8, 2015; December 7, 2015; February 10, 2016; and February 25, 2016, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated March 16, 2016.

No significant hazards consideration comments received: No.

*Entergy Nuclear Vermont Yankee, LLC and Entergy Nuclear Operations, Inc., Docket No. 50-271, Vermont Yankee Nuclear Power Station (VY), Vernon, Vermont*

*Date of amendment request:* June 24, 2015.

*Brief description of amendment request:* The amendment changed the VY Cyber Security Plan Implementation Schedule Milestone 8 full implementation date of June 30, 2016, to December 15, 2017. The amendment also revised the existing Renewed Facility Operating License Security Plan license condition.

*Date of issuance:* March 14, 2016.

*Effective date:* As of the date of issuance, and shall be implemented by June 30, 2015.

*Amendment No.:* 265. A publicly-available version is in ADAMS under Accession No. ML16014A169; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

*Renewed Facility Operating License No. DPR-28:* The amendment revised the Facility Operating License.

*Date of initial notice in Federal Register:* September 8, 2015 (80 FR 53900).

The Commission's related evaluation of this amendment is contained in the Safety Evaluation dated March 14, 2016.

No significant hazards consideration comments received: No.

*Exelon Generation Company, LLC, Docket Nos. 50-317 and 50-318, Calvert Cliffs Nuclear Power Plant, Units 1 and 2, Calvert County, Maryland*

*Exelon Generation Company, LLC, Docket Nos. 50-220 and 50-410, Nine Mile Point Nuclear Station, Units 1 and 2, Oswego County, New York*

*Exelon Generation Company, LLC, Docket No. 50-244, R.E. Ginna Nuclear Power Plant, Wayne County, New York*

*Date of amendment request:* July 29, 2015, as supplemented by letter dated November 4, 2015.

*Brief description of amendments:* The amendments revised the emergency plan definition of annual training frequency to “once per calendar year not to exceed 18 months between training sessions.”

*Date of issuance:* March 17, 2016.

*Effective date:* As of the date of issuance and shall be implemented within 90 days from the date of issuance.

*Amendment Nos.:* 316/294; 221/155; and 121. A publicly-available version is in ADAMS under Accession No. ML15352A164; documents related to these amendments are listed in the safety evaluation enclosed with the amendments.

*Renewed Facility Operating License Nos. DPR-53, DPR-69, DPR-63, NPF-69, and DPR-18:* The amendments revised the emergency plans.

*Date of initial notice in Federal Register:* December 8, 2015 (80 FR 76320).

The Commission’s related evaluation of the amendments is contained in a safety evaluation dated March 17, 2016.

No significant hazards consideration comments received: No.

*Exelon Generation Company, LLC, Docket No. 50-352, Limerick Generating Station (LGS), Unit 1, Montgomery County, Pennsylvania*

*Date of amendment request:* November 19, 2015.

*Brief description of amendment:* The amendment revised the technical specifications (TSs) related to the safety limit minimum critical power ratios. The changes resulted from a cycle-specific analysis performed to support the operation of LGS, Unit 1, in the upcoming Cycle 17.

*Date of issuance:* March 15, 2016.

*Effective date:* As of the date of issuance and shall be implemented prior to startup from the spring 2016 refueling outage.

*Amendment No.:* 221. A publicly-available version is in ADAMS under Accession No. ML16041A021; documents related to this amendment

are listed in the Safety Evaluation enclosed with the amendment.

*Renewed Facility Operating License No. NPF-39:* Amendment revised the Renewed Facility Operating License and TSs.

*Date of initial notice in Federal Register:* January 5, 2016 (81 FR 275).

The Commission’s related evaluation of the amendment is contained in a Safety Evaluation dated March 15, 2016.

No significant hazards consideration comments received: No.

*Exelon Generation Company, LLC and PSEG Nuclear LLC, Docket Nos. 50-277 and 50-278, Peach Bottom Atomic Power Station, Units 2 and 3, York and Lancaster Counties, Pennsylvania*

*Date of amendment request:* September 4, 2014, as supplemented by letters dated January 29, February 6, April 28, July 6, September 4, October 1, and October 26, 2015, and January 15, 2016.

*Brief description of amendments:* The amendments changed the Technical Specifications (TSs) and Renewed Facility Operating Licenses (RFOLs) to allow plant operation from the currently licensed Maximum Extended Load Line Limit Analysis (MELLLA) domain to plant operation in the expanded MELLLA Plus (MELLLA+) domain under the previously approved extended power uprate conditions of 3,951 megawatts thermal rated core thermal power. The expanded MELLLA+ operating domain increases operating flexibility by allowing control of reactivity at maximum power by changing flow rather than by control rod insertion and withdrawal.

*Date of issuance:* March 21, 2016.

*Effective date:* As of the date of issuance and shall be implemented within 1 year of issuance.

*Amendments Nos.:* 305 and 309. A publicly-available version is in ADAMS under Accession No. s; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

*RFOL Nos. DPR-44 and DPR-56:* The amendments revised the RFOLs and TSs.

*Date of initial notice in Federal Register:* December 2, 2014 (79 FR 71454). The supplemental letters dated January 29, February 6, April 28, July 6, September 4, October 1, and October 26, 2015, and January 15, 2016, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff’s original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission’s related evaluation of the amendments is contained in a Safety Evaluation dated March 21, 2016. No significant hazards consideration comments received: Yes.

*South Carolina Electric & Gas Company, Docket Nos. 52-027 and 52-028, Virgil C. Summer Nuclear Station (VCSNS), Units 2 and 3, Fairfield County, South Carolina*

*Date of amendment request:* September 11, 2014, as supplemented by letters dated October 15, 2014, and December 18, 2014.

*Description of amendment:* The amendments revised the Updated Final Safety Analysis Report by clarifying how human diversity was applied during the design process for the Component Interface Module and Diverse Actuation System.

*Date of issuance:* July 17, 2015.

*Effective date:* As of the date of issuance and shall be implemented within 30 days of issuance.

*Amendment Nos.:* 28. A publicly-available version is in ADAMS under Accession No. ML15176A703; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

*Facility Combined License Nos. NPF-93 and NPF-94:* Amendments revised the Facility Combined Licenses.

*Date of initial notice in Federal Register:* December 9, 2014 (79 FR 73111). The supplemental letters dated October 15, 2014, and December 18, 2014, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff’s original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission’s related evaluation of the amendments is contained in a Safety Evaluation dated July 17, 2015.

No significant hazards consideration comments received: No.

*South Carolina Electric and Gas Company, Docket Nos. 52-027 and 52-028, Virgil C. Summer Nuclear Station (VCSNS), Units 2 and 3, Fairfield County, South Carolina*

*Date of amendment request:* February 10, 2015.

*Brief description of amendment:* The amendments revised the VCSNS Units 2 and 3 Updated Final Safety Analysis Report (UFSAR) by revising the references to human factors-related plans. The UFSAR-referenced plans are the Human Factors Engineering Design Verification plan, Task Support Verification plan, and the Integrated

System Validation plan. The UFSAR references to those plans required an update to the latest version of those plans due to changes within the plans. The amendments involved changes to the approved VCSNS Units 2 and 3 UFSAR Tier 2\* information, as defined in 10 CFR part 52, appendix D, section II.F.

*Date of issuance:* September 23, 2015.

*Effective date:* As of the date of issuance and shall be implemented within 30 days of issuance.

*Amendment Nos.:* 33. A publicly-available version is in ADAMS under Accession No. ML15189A363; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

*Facility Combined License Nos. NPF-93 and NPF-94:* Amendments revised the Facility Combined Licenses.

*Date of initial notice in Federal Register:* March 31, 2015 (80 FR 17094). The supplemental letter dated March 24, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated September 23, 2015.

No significant hazards consideration comments received: No.

*South Carolina Electric & Gas Company, Docket Nos. 52-027 and 52-028, Virgil C. Summer Nuclear Station (VCSNS), Units 2 and 3, Fairfield County, South Carolina*

*Date of amendment request:* August 24, 2015.

*Brief description of amendment:* The amendments authorized changes to the VCSNS Units 2 and 3 Updated Final Safety Analysis Report Tier 2 and Tier 2\* information to revise the seismic Category I and II structures containing mechanical couplers welded to structural steel utilizing combined partial joint penetration weld with fillet weld reinforcement with fillet welds satisfying the minimum size requirements for C2/C3J couplers to demonstrate the capacity required by code is established by appropriate analyses and testing.

*Date of issuance:* November 12, 2015.

*Effective date:* As of the date of issuance and shall be implemented within 30 days of issuance.

*Amendment Nos.:* 36. A publicly-available version is in ADAMS under Accession No. ML15301A100;

documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

*Facility Combined License Nos. NPF-93 and NPF-94:* Amendments revised the Facility Combined Licenses.

*Date of initial notice in Federal Register:* September 3, 2015 (80 FR 53336). The supplemental letters dated September 23, 2015, and October 1, 2015, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated November 12, 2015.

No significant hazards consideration comments received: No.

*South Carolina Electric & Gas Company, Docket Nos. 52-027 and 52-028, Virgil C. Summer Nuclear Station (VCSNS), Units 2 and 3, Fairfield County, South Carolina*

*Date of amendment request:* October 22, 2015.

*Brief description of amendment:* The amendments authorized changes to the VCSNS Combined Licenses (COLs). Specifically, the changes were to VCSNS Units 2 and 3 COLs, Appendix A, Technical Specifications, Section 5.0, "Administrative Controls," by revising the title "Shift Supervisor" to "Shift Manager."

*Date of issuance:* February 29, 2016.

*Effective date:* As of the date of issuance and shall be implemented within 30 days of issuance.

*Amendment Nos.:* 42. A publicly-available version is in ADAMS under Accession No. ML16042A476; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

*Facility Combined License Nos. NPF-93 and NPF-94:* Amendment revised the Facility Combined Licenses.

*Date of initial notice in Federal Register:* November 24, 2015 (80 FR 73242).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated February 29, 2016.

No significant hazards consideration comments received: No.

*Southern Nuclear Operating Company, Inc., Docket Nos. 50-424 and 50-425, Vogtle Electric Generating Plant, Units 1 and 2, Burke County, Georgia*

*Date of amendment request:* May 12, 2015, as supplemented by letters dated

September 21, 2015; November 25, 2015; and January 28, 2016.

*Brief description of amendments:* The amendments revised and added Surveillance Requirements to verify that the system locations susceptible to gas accumulation are sufficiently filled with water and to provide allowances that permit performance of the verification. The changes are consistent with TSTF-523, Revision 2, "Generic Letter 2008-01, Managing Gas Accumulation."

*Date of issuance:* March 21, 2016.

*Effective date:* As of the date of issuance and shall be implemented within 120 days of issuance.

*Amendment Nos.:* 178 (Unit 1) and 159 (Unit 2). A publicly-available version is in ADAMS under Accession No. ML16063A475, documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

*Facility Operating License Nos. NPF-2 and NPF-8:* The amendments revised the Renewed Facility Operating Licenses and Technical Specifications.

*Date of initial notice in Federal Register:* June 23, 2015 (80 FR 35984).

The supplemental letters dated September 21, 2015; November 25, 2015; and January 28, 2016, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated March 21, 2016.

No significant hazards consideration comments received: No.

*Southern Nuclear Operating Company, Inc., Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket Nos. 50-321 and 50-366, Edwin I. Hatch Nuclear Plant, Unit Nos. 1 and 2, Appling County, Georgia*

*Date of amendment request:* April 2, 2015, as supplemented by letters dated November 12, 2015, and February 9, 2016.

*Brief description of amendments:* The amendments revised the technical specifications (TSs) as necessary to relocate the pressure and temperature (P-T or P/T) limit curves and associated references to a pressure and temperature limits report (PTLR). Specifically, the request modified Section 1.0, "Definitions"; Limiting Conditions for Operation and Surveillance Requirement Applicability Section 3.4.9, "RCS Pressure and Temperature

(P/T) Limits”; and Section 5.0, “Administrative Controls,” of the TSs for both units to delete reference to the P–T curves and to include reference to the unit-specific PTLRs. The amendments also implemented new P–T limits for both units.

*Date of issuance:* March 23, 2016.

*Effective date:* As of the date of issuance and shall be implemented within 90 days of issuance.

*Amendment Nos.:* 277 and 221. A publicly-available version is in ADAMS under Accession No. ML16062A099; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

*Facility Operating License Nos. DPR–57 and NPF–5:* Amendments revised the Facility Operating Licenses and TSs.

*Date of initial notice in Federal Register:* July 7, 2015 (80 FR 38760).

The supplemental letters dated November 12, 2015, and February 9, 2016, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff’s original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission’s related evaluation of the amendment is contained in a Safety Evaluation dated March 23, 2016.

No significant hazards consideration comments received: No.

*Susquehanna Nuclear, LLC, Docket Nos. 50–387 and 50–388, Susquehanna Steam Electric Station, Units 1 and 2, Luzerne County, Pennsylvania*

*Date of amendment request:* March 19, 2015, as supplemented by letters dated October 15, 2015; October 16, 2015; and January 8, 2016. A publicly-available version is in ADAMS under Accession Nos. ML15091A657, ML15296A048, ML15296A057, and ML16011A103, respectively.

*Brief description of amendments:* The amendments revised the Emergency Plan for the Susquehanna Steam Electric Station (SSES) to adopt the Nuclear Energy Institute’s (NEI’s) revised Emergency Action Level scheme described in NEI 99–01, Revision 6, “Development of Emergency Action Levels for Non-Passive Reactors” (ADAMS Accession No. ML12326A805), which was endorsed by the NRC as documented in NRC letter dated March 28, 2013 (ADAMS Accession No. ML12346A463). This request was submitted by PPL Susquehanna, LLC; however, on June 1, 2015 (ADAMS Accession No. ML15054A066), the NRC staff issued an amendment changing the name on the SESS license from PPL

Susquehanna, LLC to Susquehanna Nuclear, LLC. This amendment was issued subsequent to an order issued on April 10, 2015 (ADAMS Accession No. ML15058A073), to SSES, approving an indirect license transfer of the SESS license to Talen Energy Corporation.

*Date of issuance:* March 28, 2016.

*Effective date:* As of the date of issuance and shall be implemented on or before December 31, 2016.

*Amendment Nos.:* 265 (Unit 1) and 246 (Unit 2). A publicly-available version is in ADAMS under Accession No. ML16062A216; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

*Facility Operating License Nos. NPF–14 and NPF–22:* The amendments revised the Facility Operating Licenses.

*Date of initial notice in Federal Register:* July 7, 2015 (80 FR 38762).

The supplemental letters dated October 15, 2015; October 16, 2015; and January 8, 2016, provided additional information that clarified the application and expanded the scope of the application as originally noticed, and changed the staff’s original proposed no significant hazards consideration determination as published in the **Federal Register**. As such, the NRC staff published a subsequent notice in the **Federal Register** on February 2, 2016 (81 FR 5500).

The Commission’s related evaluation of the amendments is contained in a Safety Evaluation dated March 28, 2016.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, this 1st day of April 2016.

For the Nuclear Regulatory Commission.

**Anne T. Boland,**

*Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.*

[FR Doc. 2016–08323 Filed 4–11–16; 8:45 am]

**BILLING CODE 7590–01–P**

## NUCLEAR REGULATORY COMMISSION

[NRC–2016–0074]

### Sequoyah State-of-the-Art Reactor Consequence Analyses

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Draft technical report; public meeting and request for comment.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment draft technical report, “State-

of-the-Art Reactor Consequence Analyses (SOARCA): Sequoyah Integrated Deterministic and Uncertainty Analysis.” A public meeting related to the issuance of this draft technical report will be held on April 20, 2016. The purpose of the meeting is to present information on the pilot study for potential severe reactor accident progression and resulting offsite radiological health consequences.

**DATES:** Submit comments by May 12, 2016. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date.

**ADDRESSES:** You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC–2016–0074. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov). For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the **SUPPLEMENTARY INFORMATION** section of this document.

#### FOR FURTHER INFORMATION CONTACT:

Salman Haq, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1799; email: [Salman.Haq@nrc.gov](mailto:Salman.Haq@nrc.gov).

#### SUPPLEMENTARY INFORMATION:

### I. Obtaining Information and Submitting Comments

#### A. Obtaining Information

Please refer to Docket ID NRC–2016–0074 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC–2016–0074.
- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the

ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The draft technical report, "State-of-the-Art Reactor Consequence Analyses (SOARCA): Sequoyah Integrated Deterministic and Uncertainty Analysis," is available in ADAMS under Accession No. ML16096A374.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

#### B. Submitting Comments

Please include Docket ID NRC-2016-0074 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <http://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

#### II. Discussion

The Sequoyah SOARCA project considered a select set of potential severe reactor accidents at the Sequoyah power plant. The project combined up-to-date information about the plant's layout and operations with local population data and emergency preparedness plans. This information was then analyzed using state-of-the-art computer codes that incorporate decades of research into severe reactor accidents.

The public meeting will be held on April 20, 2016, from 6:30 p.m. to 8:00 p.m. at the Sequoyah Nuclear Plant Training Center, 2600 Igou Ferry Road, Soddy-Daisy, Tennessee 37379. The SOARCA team will hold an informal

poster session, then present the project's approach and findings, answer questions, and take comments on the draft report. The meeting agenda will be published on the NRC's Public Meeting Schedule Web site, <http://meetings.nrc.gov/pmns/mtg>, 10 days prior to the meeting. Any changes regarding the meeting will be available on the previously stated Web site.

Dated at Rockville, Maryland, this 5th day of April, 2016.

For the Nuclear Regulatory Commission,  
**Patricia A. Santiago,**  
Chief, Accident Analysis Branch, Division of Systems Analysis, Office of Nuclear Regulatory Research.

[FR Doc. 2016-08383 Filed 4-11-16; 8:45 am]

BILLING CODE 7590-01-P

#### NUCLEAR REGULATORY COMMISSION

[NRC-2016-0001]

#### Sunshine Act Meeting Notice

**DATE:** April 11, 18, 25, May 2, 9, 16, 2016.

**PLACE:** Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

**STATUS:** Public and Closed.

#### Week of April 11, 2016

There are no meetings scheduled for the week of April 11, 2016.

#### Week of April 18, 2016—Tentative

*Tuesday, April 19, 2016*

9:30 a.m.

Meeting with the Organization of Agreement States and the Conference of Radiation Control Program Directors (Public Meeting). (Contact: Paul Michalak: 301-415-5804).

This meeting will be webcast live at the Web address—<http://www.nrc.gov/>.

#### Week of April 25, 2016—Tentative

There are no meetings scheduled for the week of April 25, 2016.

#### Week of May 2, 2016—Tentative

There are no meetings scheduled for the week of May 2, 2016.

#### Week of May 9, 2016—Tentative

There are no meetings scheduled for the week of May 9, 2016.

#### Week of May 16, 2016—Tentative

*Tuesday, May 17, 2016*

9:00 a.m.

Briefing on the Status of Lessons Learned from the Fukushima Dai-

ichi Accident (Public Meeting).

(Contact: Kevin Witt: 301-415-2145)

This meeting will be webcast live at the Web address—<http://www.nrc.gov/>.

*Thursday, May 19, 2016*

10:00 a.m.

Briefing on Security Issues (Closed Ex. 1)

1:30 p.m.

Briefing on Security Issues (Closed Ex. 1)

\* \* \* \* \*

The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Denise McGovern at 301-415-0681 or via email at [Denise.McGovern@nrc.gov](mailto:Denise.McGovern@nrc.gov).

\* \* \* \* \*

The NRC Commission Meeting Schedule can be found on the Internet at:

<http://www.nrc.gov/public-involve/public-meetings/schedule.html>.

\* \* \* \* \*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (e.g. braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301-287-0739, by videophone at 240-428-3217, or by email at [Kimberly.Meyer-Chambers@nrc.gov](mailto:Kimberly.Meyer-Chambers@nrc.gov). Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

\* \* \* \* \*

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301-415-1969), or email [Brenda.Akstulewicz@nrc.gov](mailto:Brenda.Akstulewicz@nrc.gov) or [Patricia.Jimenez@nrc.gov](mailto:Patricia.Jimenez@nrc.gov).

Dated: April 8, 2016.

**Denise McGovern,**

Policy Coordinator, Office of the Secretary.

[FR Doc. 2016-08486 Filed 4-8-16; 4:15 pm]

BILLING CODE 7590-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32066; 812-14514]

### Türkiye Sinai Kalkınma Bankası A.Ş.; Notice of Application

April 6, 2016.

**AGENCY:** Securities and Exchange Commission (the “Commission”).

**ACTION:** Notice of application for an order under section 6(c) of the Investment Company Act of 1940 (“Act”) for an exemption from all provisions of the Act.

#### SUMMARY:

*Applicant:* Türkiye Sinai Kalkınma Bankası A.Ş. (“Applicant”).

*Summary of Application:* Applicant, a banking institution organized as a public joint stock company of unlimited duration under the laws of the Republic of Turkey (“Turkey”) requests an order exempting it from all provisions of the Act in connection with the offer and sale of its debt securities in the United States.

*Filing Dates:* The application was filed on July 14, 2015, and amended on November 25, 2015 and March 14, 2016.

*Hearing or Notification of Hearing:* An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission’s Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on May 2, 2016, and should be accompanied by proof of service on applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer’s interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission’s Secretary.

**ADDRESSES:** Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090. Applicant, Meclis-i Mebusan Caddesi No. 81 34427 Fındıklı, Istanbul, Turkey.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth G. Miller, Senior Counsel, at (202) 551-8707, or Holly Hunter-Ceci, Branch Chief, at (202) 551-6825 (Division of Investment Management, Chief Counsel’s Office).

**SUPPLEMENTARY INFORMATION:** The following is a summary of the application. The complete application may be obtained via the Commission’s Web site by searching for the file

number, or applicant using the Company name box, at <http://www.sec.gov/search/search.htm> or by calling (202) 551-8090.

#### Applicant’s Representations

1. Applicant is a banking institution organized as a public joint stock company of unlimited duration under the laws of Turkey. Applicant was established on May 31, 1950 as a “Development and Investment Bank” in accordance with Turkish Banking Law, No. 5411. As mandated by Turkish law, Applicant’s principal activity is promotion of Turkish economic development through providing long-term funding for domestic and international investment by Turkish companies, primarily through loans denominated in foreign currencies. The Applicant’s mandate as a “Development and Investment Bank” is to extend medium- to long-term financing to business enterprises, to assist domestic and foreign capital owners to finance the development of new businesses in Turkey, and to contribute to improvements in Turkish capital markets. A majority of Applicant’s assets, together with its consolidated financial subsidiaries (the “Group”), currently consist of loans and leasing receivables net of allowance for possible losses and a securities portfolio (of which 91.7% constituted Turkish government securities). Since such securities and loans could be considered “investment securities” within the meaning of section 3(a)(1)(C) of the Act, Applicant may be considered an investment company, and it requests an exemption from all provisions of the Act.

2. As a Turkish development and industrial bank, Applicant (i) supports private sector, productive investments in the Turkish industrial and service sectors; (ii) assists with the financing and development of new businesses in Turkey; and (iii) contributes to the improvement of Turkish capital markets. Applicant may engage, *inter alia*, in the following activities in pursuit of its development banking activities: (i) Provision of short-, medium- and long-term loan financing against pledges, mortgages, or other security by way of open credits; financing of existing and new industrial enterprises; (iii) performance of capital market or money market transactions in Turkey and abroad in cooperation with national or international institutions; (iv) financial leasing transactions and other similar financial transactions and issuance of guarantees; and (v) acceptance, establishment, and termination of mortgages. Applicant is

authorized to engage in the following standard commercial and investment banking activities: (i) “Activities of banks (including participation banks, saving banks, credit unions, *etc.*; except central banks and investment banks)”;

(ii) “Investment banking activities”;

(iii) “Activities for security incomes on own account (dividends, bank interest, participation earnings, remuneration, *etc.*)”;

(iv) “Finance leasing”;

(v) “Fund management activities bas[ed] on a fee or contract basis (portfolio management, mutual fund management, pension fund management, *etc.*)”;

and (vi) “Activities auxiliary to investment banking (mergers and acquisitions activities, business financing and venture capital financing activities, *etc.*)”.

3. As of December 31, 2015, Applicant is privately controlled, with 50.3% of its shares held directly or indirectly by Türkiye İş Bankası A.Ş. Group and 8.4% by Türkiye Vakıflar Bankası T.A.O. As of the same date, 39.3% of Applicant’s shares were publicly traded on the Borsa İstanbul A.Ş. (“BIST”) (of which 59.3% were held by foreign investors), with the remaining shares owned by various other institutional investors. A significant portion of the Group’s obligations is subject to a guarantee by the Turkish Treasury.

4. Applicant is subject to a regulatory regime substantially equivalent to that of commercial banks in Turkey, including oversight and supervision by the Turkish Banking Regulation and Supervision Agency (the “BRSA”), the Central Bank of Turkey (the “Central Bank”), the Capital Markets Board of Turkey, the BIST, the Turkish Banks Association, and the Financial Crimes Investigation Board, including a full range of banking, competition, antitrust, anti-money laundering, sanctions and other laws and regulations designed to maintain the safety and financial soundness of Turkish banks, ensure their compliance with economic and other obligations, and limit their exposure to risk. Applicant is subject to extensive oversight, supervision, and regulation by the Turkish government on the same terms as other large commercial banks, including in accordance with the Basel III framework and international capital and liquidity standards. The Turkish Treasury guarantees a significant portion of Applicant’s long-term funding from development financial institutions and appoints a representative to Applicant’s Board of Directors. Applicant’s Board of Directors and management have implemented comprehensive policies and procedures governing Applicant’s banking operations.



5. As described more fully in the application, while Applicant performs many of the same functions as Turkish commercial banks and is subject to extensive supervision and regulation by the Turkish government, Applicant is prohibited from accepting deposits from the public. The scope of Applicant's operations is more limited than that of Turkish commercial banks owing to its specific objectives as a development and investment bank.

6. Development financial institutions ("DFIs") are Applicant's primary source of funding; however, as DFI funding is typically received in the form of "tied loans" limited to a specific purpose or sector within Turkey, Applicant plans to offer and sell debt securities to supplement its funding base. Accordingly, Applicant proposes to issue and sell its debt securities in the United States from time to time, including under its Global Medium Term Note Program. Applicant intends to use the proceeds of any such sale of securities as an additional source of funding for its general purposes and in connection with its development and investment banking mandate. The proceeds of any such sale of debt securities will be used by Applicant as an additional source of funding for its general corporate purposes and in connection with its development and investment banking mandate. Specifically, Applicant intends to use any such debt security funding to extend loans to public-private partnerships and other socially responsible investment projects, including health, education, and renewable energy projects, that are ineligible for DFI tied loan funding.

#### Applicant's Legal Analysis

1. Section 3(a)(1)(C) of the Act defines an "investment company" to include any issuer engaged in the business of investing, reinvesting, owning, holding or trading in securities, and that owns or proposes to acquire investment securities having a value exceeding 40% of the issuer's total assets. Section 3(a)(2) of the Act defines "investment securities" to include all securities except Government securities, securities issued by employees' securities companies, and securities issued by majority-owned subsidiaries of the owner which (a) are not investment companies, and (b) are not relying on the exclusions from the definition of investment company in section 3(c)(1) or 3(c)(7) of the Act.

2. Applicant states that as of December 31, 2015, the Group had total assets of TL21.4 billion, of which loans and leasing receivables net of allowance

for possible losses accounted for 63.8% and the Group's securities portfolio for 18.0% (of which 91.7% constituted Turkish government securities). Such loans and securities could be construed as "investment securities" within the meaning of Section 3(a)(1)(C) of the Act, thus potentially rendering Applicant a *prima facie* "investment company." As a result, Applicant states that it could be deemed to be an "investment company" under section 3(a)(1)(C) of the Act.

3. Section 6(c) of the Act provides, in relevant part, that the Commission, by order upon application, may conditionally or unconditionally exempt any person, security, or transaction from any provision of the Act, if and to the extent necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

4. Rule 3a-6 under the Act excludes foreign banks from the definition of an investment company under the Act. A "foreign bank" is defined in the rule to include a banking institution "engaged substantially in commercial banking activity" which in turn is defined to include "extending commercial and other types of credit, and accepting demand and other types of deposits." Applicant represents that it is the functional equivalent of a "foreign bank" insofar as it (i) offers financial services and issues financial products similar to those offered and issued by other Turkish commercial banks and (ii) is subject to extensive oversight, supervision, and regulation as a bank by the Turkish government. However, by Turkish law, Applicant is prohibited from accepting deposits. Therefore, Applicant states that there is uncertainty as to whether the Rule 3a-6 exemption would be deemed to apply.

5. Applicant also believes that the rationale of Congress and the Commission in promulgating rules under the Act in exempting foreign financial institutions applies to Applicant. Applicant represents that it is subject to extensive oversight, supervision and regulation by the Turkish Government to an equivalent extent as applies to Turkish commercial banks. Applicant further represents that it is subject to a more direct form of government oversight and supervision than commercial banks in Turkey owing to representation of the Turkish Treasury on the Applicant's board of Directors and the Turkish government's guarantee of certain of the Group's liabilities. Applicant also represents that the Turkish government guarantees a significant portion of the Group's

obligation and the Turkish Treasury appoints a representative to Applicant's Board of Directors. Accordingly, Applicant represents that its operations do not lend themselves to the abuses against which the Act is directed, and states that it believes it satisfies the standards for relief under section 6(c) of the Act.

#### Applicant's Conditions

Applicant agrees that the order granting the requested relief will be subject to the following conditions:

1. In connection with any offering by Applicant of its debt securities in the United States, Applicant will appoint an agent in the United States to accept service of process in any suit, action, or proceeding brought with respect to such debt securities instituted in any state or federal court in the Borough of Manhattan, The City of New York, New York. Applicant will expressly submit to the jurisdiction of New York State and U.S. federal courts sitting in the Borough of Manhattan, The City of New York, New York, with respect to any such suit, action, or proceeding. Applicant also will waive the defense of *forum non conveniens* to the maintenance of any such action or proceeding. Such appointment of an agent to accept service of process and such consent to jurisdiction shall be irrevocable until all amounts due and to become due in respect thereof have been paid. No such submission to jurisdiction or appointment of agent for service of process shall affect the right of a holder of any such security to bring suit in any court which shall have jurisdiction over Applicant by virtue of the offer and sale of such securities or otherwise.

2. Applicant undertakes to provide to any person to which it offers its debt securities in the United States disclosure documents that are at least so comprehensive in their description of Applicant and its business as those which may be used by comparable U.S. issuers in similar U.S. offerings of such securities and that contain the latest available audited annual financial statements (and, if available, reviewed interim financial statements) of the Group. Applicant further undertakes to ensure that any underwriter or dealer through whom it makes such offers will provide such disclosure documents to each person to whom such offers are made prior to any sale of securities to such offeree. Such documents will be updated promptly to reflect any material change in the Group's financial status and shall be at least as comprehensive as offering memoranda customarily used in similar offerings in the United States. Any offering of Applicant's securities in

the United States shall comply with applicable U.S. securities and anti-fraud laws and regulations.

3. Applicant shall rely upon the order so long as (i) its activities conform in all material respects to the activities described in this Application and (ii) Applicant continues to be regulated by the BRSA, the Central Bank, or other applicable Turkish regulatory authorities as a development and investment bank as described in the application.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

**Robert W. Errett,**

*Deputy Secretary.*

[FR Doc. 2016-08298 Filed 4-11-16; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

### In the Matter of Royale Globe Holding Inc., File No. 500-1; Order of Suspension of Trading

April 8, 2016.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Royale Globe Holding Inc. because of questions regarding the accuracy of publicly available information about the company's operations and securities ownership, including details about its affiliation with Maxim Capital Limited, a purported investment company operating under the name Maxim Trader. Royale Globe Holding Inc. is delinquent in its periodic filings with the Commission, having not filed any periodic reports since it filed its Form 10-Q for the period ended July 31, 2015. Royale Globe Holding Inc. (CIK No. 0001383145), is a Nevada corporation with its principal place of business listed as Kuala Lumpur, Malaysia with stock quoted on OTC Link (previously, "Pink Sheets") operated by OTC Markets Group, Inc. under the ticker symbol ROGP.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed company.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed company is suspended for the period from 9:30 a.m. EDT, April 8, 2016, through 11:59 p.m. EDT, on April 21, 2016.

By the Commission.

**Jill M. Peterson,**

*Assistant Secretary.*

[FR Doc. 2016-08484 Filed 4-8-16; 4:15 pm]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-77547; File No. SR-CBOE-2016-021]

### Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Establish Fees for Options That Overlie a Reduced Value of the FTSE 100 Index and the FTSE China 50 Index

April 6, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on March 24, 2016, Chicago Board Options Exchange, Incorporated (the "Exchange" or "CBOE") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to establish fees for options that overlie a reduced value of the FTSE 100 Index and the FTSE China 50 Index. The text of the proposed rule change is available on the Exchange's Web site (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set

forth in sections A, B, and C below, of the most significant aspects of such statements.

#### A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

##### 1. Purpose

The Exchange proposes to amend its Fees Schedule, effective March 29, 2016. Specifically, commencing March 29, 2016, the Exchange will list new options on two FTSE Russell indexes. More specifically, the Exchange proposes to establish fees for options that overlie a reduced value of the FTSE 100 Index ("UKXM") and the China 50 Index ("FXTM").

By way of background, a specific set of proprietary products are commonly included or excluded from a variety of programs, qualification calculations and transaction fees. In lieu of listing out these products in various sections of the Fees Schedule, the Exchange uses the term "Underlying Symbol List A" to represent these products. Currently, Underlying Symbol List A is defined in Footnote 34 and represents the following proprietary products: OEX, XEO, RUT, RLG, RLV, RUI, SPX (including SPXw), SPXpm, SRO, VIX, VOLATILITY INDEXES and binary options. The Exchange notes that the reason the products in Underlying Symbol List A are often collectively included or excluded from certain programs, qualification calculations and transactions fees is because the Exchange has expended considerable resources developing and maintaining its proprietary, exclusively-listed products. Similar to the products currently represented by "Underlying Symbol List A," UKXM and FXTM are not listed on any other exchange. As such, the Exchange proposes to exclude or include UKXM and FXTM in the same programs as the other products in Underlying Symbol List A, as well as add UKXM and FXTM to the definition of Underlying Symbol List A in Footnote 34. Specifically, like the other products in Underlying Symbol List A, the Exchange proposes to except UKXM and FXTM from the Liquidity Provider Sliding Scale, the Volume Incentive Program (VIP), the Marketing Fee, the Clearing Trading Permit Holder Fee Cap ("Fee Cap") and [sic] exemption from fees for facilitation orders, and the Order Router Subsidy (ORS) and Complex Order Router Subsidy (CORS) Programs. Like all other products in Underlying Symbol List A (with the exception of SROs), the Exchange proposes to apply to UKXM and FXTM

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

the CBOE Proprietary Products Sliding Scale. The Exchange does intend to keep UKXM and FXTM volume in the calculation of qualifying volume for the rebate of Floor Broker Trading Permit fees. The Exchange notes that although UKXM and FXTM are being added to “Underlying Symbol List A”, it wishes to include UKXM and FXTM in the

calculation of the qualifying volume for the rebate of Floor Broker Trading Permit fees. The Exchange wishes to continue to encourage Floor Brokers to execute open-outcry trades in these classes and believes that including them in the qualifying volume will provide such incentive.

The Exchange next proposes to establish transaction fees for UKXM and FXTM. Particularly, the Exchange proposes to assess the same fees for UKXM and FXTM as apply to RUT, RUI, RLV and RLG options. Transaction fees for UKXM and FXTM options will be as follows (all listed rates are per contract):

Customer .....	\$0.18
Clearing Trading Permit Holder Proprietary .....	0.25
CBOE Market-Maker/DPM .....	0.20
Joint Back-Office, Broker-Dealer, Non-Trading Permit Holder Market-Maker, Professional/Voluntary Professional (non-AIM Electronic) .....	0.65
Joint Back-Office, Broker-Dealer, Non-Trading Permit Holder Market-Maker, Professional/Voluntary Professional (Manual and AIM) .....	0.25

The Exchange also proposes to apply to UKXM and FXTM, like RUI, RLV, and RLG, and RUT, the Floor Brokerage Fee of \$0.04 per contract (\$0.02 per contract for crossed orders). The Exchange also proposes to apply to UKXM and FXTM the CFLEX Surcharge Fee of \$0.10 per contract for all UKXM and FXTM orders executed electronically on CFLEX, capped at \$250 per trade (i.e., first 2,500 contracts per trade). The CFLEX Surcharge Fee assists the Exchange in recouping the cost of developing and maintaining the CFLEX system. The Exchange notes that the CFLEX Surcharge Fee (and \$250 cap) also applies to other proprietary index options, including products in Underlying Symbol List A.

The Exchange currently assesses an Index License Surcharge for RUT of \$0.45 per contract for all non-customer orders. Because the fees associated with the license for UKXM and FXTM are lower than the license fees for RUT, the Exchange proposes to assess a Surcharge of \$0.10 per contract in order to recoup the costs associated with the UKXM and FXTM license.

In order to promote and encourage trading of UKXM and FXTM, the Exchange proposes to waive all transaction fees (including the Floor Brokerage Fee, Index License Surcharge and CFLEX Surcharge Fee) for UKXM and FXTM transactions through September 30, 2016. In order to promote and encourage trading of RUI, RLV and RLG, the Exchange also proposes to extend the waiver of transaction fees (including the Floor Brokerage Fee, Index License Surcharge and CFLEX Surcharge Fee) for RUI, RLV and RLG. The Exchange proposes to amend Footnote 40 to the Fees Schedule to make clear that transaction fees for RUI, RLV, RLG, UKXM and FXTM will be waived through September 30, 2016.

The Exchange is also offering a compensation plan to the Designated

Primary Market-Maker(s) (“DPM(s)”) appointed in FXTM or UKXM to offset the initial DPM costs. The Exchange proposes to add Footnote 43 to the Fees Schedule that provides that DPM(s) appointed for an entire month in either FXTM or UKXM will receive a payment of \$5,000 per class per month through December 31, 2016. Because FXTM and UKXM are scheduled to be listed on March 29, 2016, the appointed DPM(s) will not have an appointment in FXTM or UKXM for the entire month of March; thus, the DPM(s) will not receive compensation for March 2016. The DPM(s) appointed for the entire month of April, May, etc. will receive compensation of \$5,000 for each entire month the DPM is appointed in FXTM or UKXM through December 31, 2016.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the “Act”) and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.<sup>3</sup> Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)<sup>4</sup> requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with

Section 6(b)(4) of the Act,<sup>5</sup> which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Trading Permit Holders and other persons using its facilities.

Particularly, the Exchange believes it is reasonable to charge different fee amounts to different user types in the manner proposed because the proposed fees are consistent with the price differentiation that exists today for other index products, including RUT, RUI, RLV, and RLG. The Exchange also believes that the proposed fee amounts for UKXM and FXTM orders are reasonable because the proposed fee amounts are the same already assessed for similar products (e.g., RUT, RUI, RLV, and RLG), as well as are within the range of amounts assessed for the Exchange’s other proprietary products.<sup>6</sup>

The Exchange believes that it is equitable and not unfairly discriminatory to assess lower fees to Customers as compared to other market participants because Customer order flow enhances liquidity on the Exchange for the benefit of all market participants. Specifically, customer liquidity benefits all market participants by providing more trading opportunities, which attracts Market-Makers. An increase in the activity of these market participants in turn facilitates tighter spreads, which may cause an additional corresponding increase in order flow from other market participants. The fees offered to customers are intended to attract more customer trading volume to the Exchange. Moreover, the options industry has a long history of providing preferential pricing to Customers, and the Exchange’s current Fees Schedule currently does so in many places, as do

<sup>3</sup> 15 U.S.C. 78f(b).

<sup>4</sup> 15 U.S.C. 78f(b)(5).

<sup>5</sup> 15 U.S.C. 78f(b)(4).

<sup>6</sup> See CBOE Fees Schedule, Specified Proprietary Index Options Rate Table.

the fees structures of many other exchanges. Finally, all fee amounts listed as applying to Customers will be applied equally to all Customers (meaning that all Customers will be assessed the same amount).

The Exchange believes that it is equitable and not unfairly discriminatory to, [sic] assess lower fees to Market-Makers as compared to other market participants other than Customers because Market-Makers, unlike other market participants, take on a number of obligations, including quoting obligations, that other market participants do not have. Further, these lower fees offered to Market-Makers are intended to incent Market-Makers to quote and trade more on the Exchange, thereby providing more trading opportunities for all market participants. Additionally, the proposed fee for Market-Makers will be applied equally to all Market-Makers (meaning that all Market-Makers will be assessed the same amount). This concept also applies to orders from all other origins. It should also be noted that all fee amounts described herein are intended to attract greater order flow to the Exchange in UKXM and FXTM which should therefore serve to benefit all Exchange market participants. Similarly, it is equitable and not unfairly discriminatory to assess lower fees to Clearing Trading Permit Holder Proprietary orders than those of other market participants (except Customers and Market-Makers) because Clearing Trading Permit Holders also have a number of obligations (such as membership with the Options Clearing Corporation), significant regulatory burdens, and financial obligations, that other market participants do not need to take on. The Exchange also notes that the UKXM and FXTM fee amounts for each separate type of market participant will be assessed equally to all such market participants (*i.e.* all Broker-Dealer orders will be assessed the same amount, all Joint Back-Office orders will be assessed the same amount, etc.).

The Exchange believes the proposed AIM transaction fees for Brokers Dealers, Non-Trading Permit Holder Market-Makers, Professionals/Voluntary Professionals, JBOs and Customers are reasonable because the amounts are still lower than assessed for AIM transactions in other proprietary products.<sup>7</sup> The Exchange believes it's equitable and not unfairly discriminatory to assess lower fees for AIM executions as compared to electronic executions because AIM is a price-improvement mechanism, which

the Exchange wishes to encourage and support.

Assessing the Floor Brokerage Fee of \$0.04 per contract for non-crossed orders and \$0.02 per contract for crossed orders to Floor Brokers (and not other market participants) trading UKXM and FXTM orders is equitable and not unfairly discriminatory because only Floor Brokers are statutorily capable of representing orders in the trading crowd, for which they charge a commission. Moreover, this fee is already assessed, in the same amounts, to the other products in Underlying Symbol List A, including RUT, RUI, RLV, and RLG.

The Exchange believes that assessing an Index License Surcharge Fee of \$0.10 per contract to UKXM and FXTM transactions is reasonable because the Surcharge helps recoup some of the costs associated with the license for UKXM and FXTM options. Additionally, the Exchange notes that the Surcharge amount is the same as, and in some cases lower than, the amount assessed as an Index License Surcharge to other index products. The proposed Surcharge is also equitable and not unfairly discriminatory because the amount will be assessed to all market participants to whom the Surcharge applies. Not applying the UKXM and FXTM Index License Surcharge Fee to Customer orders is equitable and not unfairly discriminatory because this is designed to attract Customer UKXM and FXTM orders, which increases liquidity and provides greater trading opportunities to all market participants. Additionally, it is equitable and not unfairly discriminatory to assess a lower License Index Surcharge amount to UKXM and FXTM transactions as compared to RUT transactions because the costs of the license associated with RUT is greater.

Similarly, the Exchange believes assessing a CFLEX Surcharge Fee of \$0.10 per contract for all UKXM and FXTM orders executed electronically on CFLEX and capping it at \$250 (*i.e.*, first 2,500 contracts per trade) is reasonable because it is the same amount currently charged to other proprietary index products for the same transactions.<sup>8</sup> The proposed Surcharge is also equitable and not unfairly discriminatory because the amount will be assessed to all market participants to whom the CFLEX Surcharge applies.

Excepting UKXM and FXTM from the Liquidity Provider Sliding Scale, VIP,

<sup>7</sup> See CBOE Fees Schedule, Index Options Rate Table—All Index Products Excluding Underlying Symbol List A, CFLEX Surcharge Fee and Specified Proprietary Index Options Rate Table—Underlying Symbol List A, CFLEX Surcharge Fee.

the Marketing Fee, the Fee Cap, and [sic] the exemption from fees for facilitation orders and the ORS and CORS Programs is reasonable because other Underlying Symbol List A products (*i.e.*, other products that are exclusively-listed) are excepted from those same items. This is equitable and not unfairly discriminatory for the same reason; it seems equitable to except UKXM and FXTM from items on the Fees Schedule from which other proprietary products are also excepted.

The Exchange believes it is reasonable, equitable and not unfairly discriminatory to waive all transaction fees, including the Floor Brokerage fee, the License Index Surcharge and CFLEX Surcharge Fee because it promotes and encourages trading of these new products and applies to all Trading Permit Holders ("TPHs").

Applying to UKXM and FXTM to the CBOE Proprietary Products Sliding Scale is reasonable because it also applies to other Underlying Symbol List A products. This is equitable and not unfairly discriminatory for the same reason; it seems equitable to apply to UKXM and FXTM the same items on the Fees Schedule that apply to Underlying Symbol List A options classes (*i.e.*, proprietary options classes that are not listed on other exchanges).

The Exchange believes it's reasonable, equitable and not unfairly discriminatory to continue to include UKXM and FXTM in the calculation of the qualifying volume for the Floor Broker Trading Permit Fees rebate because the Exchange wishes to support and encourage open-outcry trading of UKXM and FXTM, which allows for price improvement and has a number of positive impacts on the market system.

Finally, the Exchange believes that it is equitable and not unfairly discriminatory to compensate DPM(s) that are appointed for an entire month in either FXTM or UKXM. DPM(s) incur costs when receiving an appointment, and in the case of FXTM and UKXM, the Exchange believes it is appropriate to provide compensation to the DPM(s) to offset those costs.

#### *B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule changes will impose any burden on competition that are not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because, while different fees are

<sup>7</sup> *Id.*

assessed to different market participants in some circumstances, these different market participants have different obligations and different circumstances as discussed above. For example, Market-Makers have quoting obligations that other market participants do not have. The Exchange does not believe that the proposed rule change to waive all transaction fees through September 30, 2016 will impose any burden on intramarket competition because it applies to all TPHs and encourages trading in these new products.

The Exchange does not believe that the proposed rule changes will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because UKXM and FXTM will be exclusively listed on CBOE. To the extent that the proposed changes make CBOE a more attractive marketplace for market participants at other exchanges, such market participants are welcome to become CBOE market participants.

### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act<sup>9</sup> and paragraph (f) of Rule 19b-4<sup>10</sup> thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will 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](mailto:rule-comments@sec.gov). Please include File Number SR-CBOE-2016-021 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-CBOE-2016-021*. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number *SR-CBOE-2016-021* and should be submitted on or before May 3, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>11</sup>

**Robert W. Errett,**

*Deputy Secretary.*

[FR Doc. 2016-08306 Filed 4-11-16; 8:45 am]

**BILLING CODE 8011-01-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 Thursday, April 14, 2016 at 1:00 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. 552(b)(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.

Chair White, as duty officer, voted to consider the items listed for the Closed Meeting in closed session.

The subject matter of the Closed Meeting will be:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

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: April 7, 2016.

**Brent J. Fields,**

*Secretary.*

[FR Doc. 2016-08446 Filed 4-8-16; 11:15 am]

**BILLING CODE 8011-01-P**

<sup>9</sup> 15 U.S.C. 78s(b)(3)(A).

<sup>10</sup> 17 CFR 240.19b-4(f).

<sup>11</sup> 17 CFR 200.30-3(a)(12).

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-77535; File No. SR-NYSEArca-2016-11]

### Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change, as Modified by Amendment No. 1 Thereto, Amending Section 4.01(a) of the NYSE Arca's Bylaws and NYSE Arca Rule 3.3 To Establish a Committee for Review as a Sub-Committee of the ROC and Making Conforming Changes to NYSE Arca Rules

April 6, 2016.

Pursuant to Section 19(b)(1)<sup>1</sup> of the Securities Exchange Act of 1934 (the "Act" or "Exchange Act")<sup>2</sup> and Rule 19b-4 thereunder,<sup>3</sup> notice is hereby given that, on March 24, 2016, 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, II, and III below, which Items have been prepared by the self-regulatory organization. On April 4, 2016, the Exchange filed Amendment No. 1 to the proposal.<sup>4</sup> The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No. 1, from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to (1) amending Section 4.01(a) of the NYSE Arca's Bylaws and NYSE Arca Rule 3.3 to establish a Committee for Review as a sub-committee of the Regulatory Oversight Committee ("ROC"), deleting NYSE Arca Rule 3.2(b)(3) governing the OTP Advisory Committee and NYSE Arca Equities Rule 3.2(b)(3) governing the Member Advisory Committee, both of whose functions will be assumed by the Committee for Review, and making conforming changes to NYSE Arca Rules 2.4, 10.3, 10.6, 10.8, 10.11, 10.12, 10.14 and NYSE Arca Equities Rules 2.3, 3.3, 5.5, 10.3, 10.6, 10.8, 10.11, 10.12, and 10.13; and (2) deleting references to "NYSE Regulation, Inc." and "NYSE Regulation" in NYSE Arca and NYSE Arca Equities Rule 0 and NYSE Arca Equities Rule 5.3(i)(1) and replacing a

reference to the "NYSE Regulation, Inc. Chief Executive Officer" in NYSE Arca Equities Rules 2.100. This Amendment No. 1 to SR-NYSEArca-2016-11 amends and replaces the original filing in its entirety. The proposed rule change is available on the Exchange's Web site at [www.nyse.com](http://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 Statutory Basis for, the Proposed Rule Change

###### 1. Purpose

The Exchange proposes the following changes to the Rules of NYSE Arca and NYSE Arca Equities:

- Amending Section 4.01(a) of the NYSE Arca's Bylaws and NYSE Arca Rule 3.3 to establish a Committee for Review ("CFR") as a sub-committee of the ROC, deleting NYSE Arca Rule 3.2(b)(3) governing the OTP Advisory Committee and NYSE Arca Equities Rule 3.2(b)(3) governing the Member Advisory Committee, both of whose functions will be assumed by the CFR, and making conforming changes to NYSE Arca Rules 2.4, 10.3, 10.6, 10.8, 10.11, 10.12, 10.14 and NYSE Arca Equities Rules 2.3, 3.3, 5.5, 10.3, 10.6, 10.8, 10.11, 10.12, and 10.13;
- Deleting references to "NYSE Regulation, Inc." and "NYSE Regulation"<sup>5</sup> in NYSE Arca and NYSE

<sup>5</sup> NYSE regulation, a not-for-profit subsidiary of the Exchange's affiliate New York Stock Exchange LLC ("NYSE"), performed regulatory functions for the Exchange pursuant to an intercompany Regulatory Services Agreement ("RSA") that gave the Exchange the contractual right to review NYSE Regulation's performance. See Securities Exchange Act Release No. 75991 (September 28, 2015), 80 FR 59837 (October 2, 2015) (SR-NYSE-2015-27) ("NYSE Approval Order"). The RSA terminated on February 16, 2016. The proposed changes relating to references to NYSE Regulation and the NYSE Regulation Chief Executive Officer are therefore appropriate because NYSE Regulation has ceased providing regulatory services to the Exchange, which has re-integrated its regulatory functions.

Arca Equities Rule 0 and NYSE Arca Equities Rule 5.3(i)(1); and

- Replacing a reference to the "NYSE Regulation, Inc. Chief Executive Officer" in NYSE Arca Equities Rule 2.100.<sup>6</sup>

###### Background

NYSE Arca, a registered securities exchange, operates a marketplace for trading options and, through its wholly-owned subsidiary NYSE Arca Equities, a marketplace for trading equities.<sup>7</sup> NYSE Arca administers the disciplinary program for the options marketplace, which encompasses investigations, adjudication of cases, and the imposition of fines and other sanctions, and has delegated disciplinary and adjudicatory functions for the equities marketplace to NYSE Arca Equities.<sup>8</sup> As summarized below, NYSE Arca and NYSE Arca Equities each utilizes its own committee structure for appeals of disciplinary decisions or summary determinations.<sup>9</sup> The Exchange proposes to amend the current appellate structure to establish a single CFR to hear appeals for both marketplaces.

###### NYSE Arca

The Exchange's disciplinary jurisdiction extends to Options Trading Permit ("OTP") Holders, OTP Firms and associated persons of an OTP Firm or OTP Holder alleged to have violated or aided and abetted a violation of any provision of the Exchange Act or the rules and regulations thereunder, any provision of the Exchange's Bylaws or Rules or any commentary thereof, any resolution of the Board of Directors of the Exchange regulating the conduct of business on the Exchange, or Exchange policy or procedure.<sup>10</sup> Disciplinary proceedings are heard by a "Conduct Panel" appointed by the NYSE Arca Ethics and Business Conduct Committee ("EBCC").<sup>11</sup>

Under current NYSE Arca Rules 3.3 and 10.8, an appeal of matters subject to the applicable provisions of NYSE Arca Rules 3.2(b)(1)(C) or 10, including a Conduct Panel decision pursuant to Rule 10.7 or summary determination pursuant to Rule 10.4(c), may be

<sup>6</sup> The Exchange would effect the proposed changes described herein no later than June 30, 2016, on a date determined by its Board.

<sup>7</sup> See NYSE Arca Rule 10.

<sup>8</sup> See NYSE Arca Equities Rule 3.4, 3.5, 14.1 & 14.2.

<sup>9</sup> A summary determination is a determination without a hearing where a penalty is imposed as to such charges that a respondent has admitted or failed to answer or which otherwise does not appear to be in dispute. See NYSE Arca Rule 10.4(c); NYSE Arca Equities Rule 10.4(c).

<sup>10</sup> See Rule 10.1.

<sup>11</sup> See NYSE Arca Rule 10.5(a).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 15 U.S.C. 78a.

<sup>3</sup> 17 CFR 240.19b-4.

<sup>4</sup> Amendment No. 1 amends and replaces the original filing in its entirety. In Amendment No. 1, the Exchange, among other things, deleted language in the description of the proposed rule change that was not relevant to the proposed rule change.

reviewed by the NYSE Arca Board Appeals Committee (“NYSE Arca BAC”) or an “Appeals Panel” appointed by the NYSE Arca BAC.<sup>12</sup> The NYSE Arca BAC is a committee of the NYSE Arca board of directors (the “SRO Board”) made up of the OTP Director(s), the ETP Director(s) and all of the Public Directors of the NYSE Arca Board of Directors.<sup>13</sup> Under current NYSE Arca Rule 3.3(a)(1)(B), if an Appeals Panel is appointed, it must include at least one Public Director and at least one Director that is an OTP Holder or Allied Person of an OTP Firm.<sup>14</sup>

#### NYSE Arca Equities

NYSE Arca Equities’ disciplinary jurisdiction extends to any ETP Holder or associated person of an ETP Holder alleged to have violated or aided and abetted a violation of any provision of the Exchange Act or the rules and regulations thereunder, any provision of NYSE Arca Equities’ Bylaws or Rules or any commentary thereof, any resolution of the Board of Directors of NYSE Arca Equities regulating the conduct of NYSE Arca Equities, or NYSE Arca Equities policy or procedure.<sup>15</sup> Similar to NYSE Arca, disciplinary proceedings of NYSE Arca Equities are heard by a “Conduct Panel” appointed by the NYSE Arca Equities Business Conduct Committee (“BCC”).<sup>16</sup>

Under current NYSE Arca Equities Rules 3.3 and 10.8, an appeal of matters subject to the applicable provisions of NYSE Arca Equities Rules 3.2(b)(1)(C), 5 or 10 may be reviewed by the NYSE Arca Equities Board Appeals Committee

<sup>12</sup> See NYSE Arca Rule 10.8. In addition, NYSE Arca Rule 3.2(b)(1)(C) provides that the NYSE Arca EBCC has the authority, whenever it appears that an OTP Firm or OTP Holder is in violation of NYSE Arca Rule 4 (Capital Requirements, Financial Reports, Margin), to direct a representative of such OTP Firm or OTP Holder to appear before the committee for examination upon 48 hours’ notice, following which the EBCC can suspend such OTP Firm or OTP Holder until the requirements of NYSE Arca Rule 4 are fully met. NYSE Arca Rule 10 governs disciplinary proceedings and appeals. Under NYSE Arca Rule 10.8, the NYSE Arca BAC has the option of appointing an Appeals Panel to review disciplinary appeals or conduct review proceedings on its own. See also note 17, *infra*.

<sup>13</sup> See Article III, Section 3.02 of the bylaws of the Exchange. An “ETP Director” is a director nominated by the Equities Trading Permit (“ETP”) Holders of NYSE Arca Equities, Inc. and an “OTP Director” is a director nominated by the OTP Holders of the Exchange. “Public Directors” of the Exchange are directors that are “persons from the public and will not be, or be affiliated with, a broker-dealer in securities or employed by, or involved in any material business relationship with, the Exchange or its affiliates”. *Id.*

<sup>14</sup> See NYSE Arca Rule 3.3(a)(1)(B). See also NYSE Arca Rule 3.2.

<sup>15</sup> See NYSE Arca Equities Rule 10.1.

<sup>16</sup> See NYSE Arca Equities Rule 10.5(a).

(“NYSE Arca Equities BAC”).<sup>17</sup> The NYSE Arca Equities BAC is an equity committee of the NYSE Arca Equities board of directors, and is made up of, in addition to any members of the public on the committee, at least one director that is an ETP Holder or Allied Person of an ETP Holder.<sup>18</sup>

#### Proposal To Establish CFR as a Sub-Committee of the ROC

In 2015, the Board established a ROC as a committee of the SRO Board.<sup>19</sup> As discussed below, the Exchange proposes to create a CFR as a sub-committee of the ROC to replace the current structure of separate NYSE Arca and NYSE Arca Equities BACs for the options and equities markets. The proposed CFR would incorporate the salient requirements of both markets’ current BAC process.

By establishing a single CFR, the Exchange proposes to make its appellate process consistent with that of its affiliates NYSE and NYSE MKT LLC (“NYSE MKT”), both of which recently established a CFR as a subcommittee of the respective affiliate’s ROC.<sup>20</sup> In particular, the Exchange proposes to incorporate the salient requirements of the NYSE and NYSE MKT CFRs.<sup>21</sup>

<sup>17</sup> NYSE Arca Equities Rule 3.2(b)(1)(C), like NYSE Arca Rule 3.2(b)(1)(C), provides that the NYSE Arca Equities BCC has the authority, whenever it appears that an ETP Holder is in violation of NYSE Arca Equities Rule 4 (Capital Requirements, Financial Reports, Margin), to direct a representative of such ETP Holder to appear before the committee for examination upon 48 hours’ notice, following which the BCC can suspend such ETP Holder until the requirements of NYSE Arca Equities Rule 4 are fully met. NYSE Arca Equities Rule 5 governs listing and continued listing requirements and delisting procedures (see NYSE Arca Equities Rule 5.5(m)). NYSE Arca does not have a comparable rule. NYSE Arca Equities Rule 10 governs disciplinary proceedings and appeals. Under NYSE Arca Equities Rule 10.8, the Board Appeals Committee has the option of appointing an Appeals Panel to review disciplinary appeals or conduct review proceedings on its own.

<sup>18</sup> See NYSE Arca Equities Rule 3.3(a)(1)(A). See also NYSE Arca Rule 3.1 & Rule 3.2.

<sup>19</sup> See Securities Exchange Act Release No. 75155 (June 11, 2015), 80 FR 34744 (June 17, 2015) (SR-NYSEArca-2015-29) (“Release No. 75155”). The Exchange does not propose to amend the provisions relating to the EBCC or BCC, which will remain separate.

<sup>20</sup> See NYSE Approval Order, 80 FR at 59840; Securities Exchange Act Release No. 77008 (February 1, 2016), 81 FR 6311, 6312 (February 5, 2016) (NYSEMKT 2015-106) (“NYSE MKT Approval Order”). The NYSE and NYSE MKT CFRs became operative on February 16, 2016 following the NYSE’s termination of the agreement delegating the NYSE’s regulatory functions to NYSE Regulation and NYSE MKT’s termination of the related RSA pursuant to which NYSE Regulation performed regulatory functions for NYSE MKT.

<sup>21</sup> The NYSE and NYSE MKT CFRs were modeled on the former committee for review of the NYSE Regulation board of directors (the “NYSE Regulation CFR”). The salient requirements of the NYSE Regulation CFR were set forth in Article III,

As proposed, the CFR would be composed of OTP Director(s) of NYSE Arca, ETP Director(s) of NYSE Arca Equities and the Public Directors of both markets<sup>22</sup> and would have the authority to appoint “CFR Appeals Panels” to conduct reviews of matters decided by the EBCC and BCC for the options and equities marketplaces, respectively. CFR Appeals Panels would also have the authority to conduct reviews of BCC determinations to limit or prohibit the continued listing of an issuer’s securities.<sup>23</sup>

To effect these changes, the Exchange proposes amending Section 4.01(a) of the NYSE Arca’s Bylaws and NYSE Arca Rule 3.3, deleting NYSE Arca Rule 3.2(b)(3) and NYSE Arca Equities Rule 3.2(b)(3), and make conforming changes to NYSE Arca Rules 2.4, 10.3, 10.6, 10.8, 10.11, 10.12, 10.14 and NYSE Arca Equities Rules 2.3, 3.3, 5.5, 10.3, 10.6, 10.8, 10.11, 10.12, and 10.13.

NYSE Arca Rule 3.1(a) provides the Board with authority to establish one or more committees consisting partly or entirely of directors of NYSE Arca. The Exchange proposes to amend NYSE Arca Rule 3.3 to provide for a CFR and delineate its composition and functions.

Proposed NYSE Arca Rule 3.3(a)(2)(A) would provide that the Board shall annually appoint a CFR as a sub-committee of the ROC.<sup>24</sup> Proposed NYSE Arca Rule 3.3(a)(2)(A) would provide that the CFR would be responsible for reviewing disciplinary decisions; reviewing determinations to limit or prohibit the continued listing of an issuer’s securities on NYSE Arca Equities; and acting in an advisory capacity to the Board with respect to disciplinary matters, the listing and delisting of securities, regulatory programs, rulemaking, and regulatory rules, including trading rules. As is currently the case for the NYSE Arca

Section 5 of the NYSE Regulation Bylaws. See Securities Exchange Act Release No. 53382, 71 FR 11251, 11259 & 11266 (February 27, 2006) (SR-NYSE-2005-77). See NYSE Approval Order, 80 FR at 59840 & NYSE MKT Approval Order, 81 FR at 6313 & n. 27.

<sup>22</sup> Article III, Section 3.02 of the NYSE Arca Bylaws and the NYSE Arca Equities Bylaws require that at least 50% of the directors be “Public Directors”, defined as persons from the public that are not affiliated with a broker-dealer in securities. The NYSE Arca Bylaws further require that a Public Director not be employed by, or involved in any material business relationship with, the Exchange or its affiliates. See note 13, *supra*.

<sup>23</sup> The NYSE Arca Equities BAC currently has the same mandate. See note 17, *supra*. The NYSE Arca BAC’s mandate does not include reviews of delisting determinations. See notes 12 & 17, *supra*.

<sup>24</sup> The Exchange proposes to delete current Rule 3.3(a)(1) which describes the Board Appeals Committee and move the text, with modifications, to proposed Rule 3.3(a)(2), following the provision regarding the ROC.

BAC, proposed Rule 3.3(a)(2) would provide that the CFR would be comprised of the OTP Director(s), the ETP Director(s) and all of the Public Directors.

#### NYSE Arca

Proposed NYSE Arca Rule 3.3(a)(2)(B) would provide that the CFR may appoint a CFR Appeals Panel made up of members of the CFR. Like the current requirements for the Appeals Panels of the NYSE Arca BAC, the proposed Rule would provide that the CFR Appeals Panel would be made up of no less than three but no more than five individuals. Proposed NYSE Arca Rule 3.3(a)(2)(B) would provide that a CFR Appeals Panel for NYSE Arca would, like current NYSE Arca BAC Appeals Panels provided for in NYSE Arca Rule 3.3(a)(1)(B), conduct reviews of matters subject to the applicable provisions of NYSE Arca Rule 3.2(b)(1)(C) or 10.<sup>25</sup>

Proposed NYSE Arca Rule 3.3(a)(2)(B) would further provide that each CFR Appeals Panel would contain at least one Public Director and at least one Director that is an OTP Holder or Allied Person or Associated Person of an OTP Firm.<sup>26</sup> This is the same as the current requirement for Appeals Panels of the NYSE Arca BAC.

Finally, proposed NYSE Arca Rule 3.3(a)(2)(C) would retain the current provision governing the NYSE Arca BAC that, subject to Rule 10, decisions

<sup>25</sup> Under current NYSE Arca and NYSE Arca Equities Rules, decisions by an Appeals Panels appointed by the Board Appeals Committee of both markets are final unless appealed to the Board of Directors or called for review by the Board of Directors. *See, e.g.*, NYSE Arca Rule 10.8(b) & (d); NYSE Arca Equities Rule 10.8(d). The Exchange proposes that CFR Appeals Panels retain this ability to resolve appeals and therefore does not propose that appellate panels appointed by the CFR would make recommendations to the CFR, as is the case with appellate panels for the Exchange's affiliate NYSE MKT, which did not previously have appellate panels. *See* NYSE MKT Approval Order, 81 FR at 6312.

<sup>26</sup> Section 6(b)(3) of the Exchange Act requires that the rules of an exchange "assure a fair representation of its members in the selection of its directors and administration of its affairs and provide that one or more directors shall be representative of issuers and investors and not be associated with a member of the exchange, broker, or dealer." 15 U.S.C. 78f(b)(3). Exchange members who serve on exchange boards thus are sometimes referred to as "fair representation directors." In 2012, the Exchange expanded the eligibility for fair representation directors to include Associated Persons of OTP Firms and Associated Persons of ETP Holders, and amended NYSE Arca Rule 3.3 and NYSE Arca Equities Rule 3.3 so that Associated Persons of OTP Firms and ETP Holders were eligible for membership on the Board Appeals Committee. *See* Securities Exchange Act Release No. 68233 (November 14, 2012), 77 FR 69677, 69677 (November 20, 2012) (SR-NYSEArca-2012-103). The Exchange proposes to carry these categories forward into proposed NYSE Arca and NYSE Arca Equities Rule 3.3.

of the CFR would be subject to SRO Board review. Proposed subsection (a)(2)(C) would also provide, like the current provision governing the NYSE Arca BAC, that the decision of the Board shall constitute the final action of NYSE Arca, unless the Board remands the proceedings.<sup>27</sup>

NYSE Arca also proposes to amend Article IV, Section 4.01(a) of its Bylaws governing board committees. Specifically, NYSE Arca proposes to replace references to the "Board Appeals Committee" with references to the "Committee for Review as a subcommittee of the Regulatory Oversight Committee" and "its subcommittee, the CFR."

NYSE Arca proposes conforming amendments to NYSE Arca Rules 2.4, 10.3, 10.6, 10.8, 10.11, 10.12, 10.14 to replace references to the Board Appeals Committee with references to the "Committee for Review" or "CFR" and references to the Appeals Panel with references to the "CFR Appeals Panel."<sup>28</sup>

#### NYSE Arca Equities

Similar conforming changes are proposed for NYSE Arca Equities. In particular, NYSE Arca Equities Rules 3.3, which mirrors NYSE Arca Rule 3.3, would be retitled "Committee for Review" and amended to provide that the SRO Board shall, on an annual basis, appoint the CFR as a sub-committee of the ROC. Proposed Rule 3.3(a)(1)(A) would provide that the CFR may, in turn, appoint a CFR Appeals Panel for NYSE Arca Equities market. Like the proposed CFR Appeals Panel for NYSE Arca, any CFR Appeals Panel appointed for NYSE Arca Equities would be made

<sup>27</sup> In this respect, the Exchange practice would differ from that of its affiliates NYSE and NYSE MKT, where a decision by the CFR would be a final action of the board of directors.

<sup>28</sup> NYSE Arca Rule 10.11(e)(1) currently provides that appellate review of Floor citations and minor rule plan sanctions shall be referred directly to an appropriate Board Appeals Committee Panel (defined as an "Appeals Panel") appointed by the NYSE Arca Board of Directors. Current NYSE Arca Rule 10.11(e)(2) governs decisions by such Appeals Panels. The Exchange proposes to replace "an appropriate Board Appeals Committee Panel ('Appeals Panel') appointed by the Board" in NYSE Arca Rule 10.11(e)(1) with "CFR." The Exchange believes that it would be more appropriate for such matters to be directly referred to the CFR, which can then determine whether to appoint a CFR Appeals Panel as is currently proposed for disciplinary appeals under NYSE Arca Rule 10.8(b). Accordingly, the Exchange proposes to add text to NYSE Arca Rule 10.11(e)(2) providing that the CFR may appoint a CFR Appeals Panel to conduct reviews under this subsection or may decide to conduct review proceedings on its own. References to the "Appeals Panel" would be replaced with "CFR or CFR Appeals Panel."

up of no less than three but no more than five individuals.<sup>29</sup>

A CFR Appeals Panel reviewing matters related to the equities market would conduct reviews of matters subject to the applicable provisions of Rules 3.2(b)(1)(C), 5 or 10.<sup>30</sup> As proposed, CFR Appeals Panels for NYSE Arca Equities would have no other role in the appellate process. Each CFR Appeals Panel would contain at least one Public Director and at least one director that is an ETP Holder or Allied Person or Associated Person of an ETP Holder.

Outdated references to the NYSE Arca Board of Governors in NYSE Arca Equities Rules 3.3(a)(1)(B) would be replaced with references to the "NYSE Arca Board of Directors." The current Rule would otherwise remain unchanged. The revised provision would thus provide that, subject to Rule 10, decisions of the CFR shall be subject to the review of the SRO Board and that the decision of the SRO Board would constitute the final action of NYSE Arca Equities, unless such SRO Board remands the proceedings.

Conforming amendments to NYSE Arca Equities Rules 2.3, 5.5, 10.3, 10.6, 10.8, 10.11,<sup>31</sup> 10.12, and 10.13<sup>32</sup> to replace references to the NYSE Arca Equities BAC with references to the "Committee for Review" or "CFR" and to replace references to the "Appeals Panel" with the "CFR Appeals Panel" are also proposed. Outdated references

<sup>29</sup> NYSE Arca Equities Rule 3.3(a)(1) currently provides that the Board of Directors will determine the size of any Appeals Committee that it appoints.

<sup>30</sup> *See* note 17, *supra*.

<sup>31</sup> NYSE Arca Equities Rule 10.11(e)(1) currently provides that appellate review of Floor citations and minor rule plan sanctions shall be referred directly to an appropriate Board Appeals Committee Panel (defined as an "Appeals Panel") appointed by the Board Appeals Committee. Current NYSE Arca Equities Rule 10.11(e)(2) governs decisions by such Appeals Panels. The Exchange proposes to replace "an appropriate Board Appeals Committee Panel ('Appeals Panel') appointed by the Board Appeals Committee" in NYSE Arca Equities Rule 10.11(e)(1) with "CFR." The Exchange believes that it would be more appropriate for such matters to be directly referred to the CFR, which can then determine whether to appoint a CFR Appeals Panel as is currently proposed for disciplinary appeals under NYSE Arca Equities Rule 10.8(b). Accordingly, the Exchange proposes to add text to NYSE Arca Equities Rule 10.11(e)(2) providing that the CFR may appoint a CFR Appeals Panel to conduct reviews under this subsection or may decide to conduct review proceedings on its own. A reference to "Appeals Panel" and two references to "Appeals Board" would be replaced with "CFR or CFR Appeals Panel." *See also* note 28, *supra*.

<sup>32</sup> The Exchange also proposes to amend the heading of NYSE Arca Equities Rule 10.13 to delete the references to "the Corporation," which refers to NYSE Arca Equities, since the hearings and review of decisions referred to therein would be conducted by the CFR, a subcommittee of the SRO Board.



to the NYSE Arca Board of Governors in NYSE Arca Equities Rules 10.3, 10.12, and 10.13 would also be replaced with references to the “NYSE Arca Board of Directors.”

#### Committees

The Exchange does not propose to retain the OTP Advisory Committee of NYSE Arca or the Member Advisory Committee of NYSE Arca Equities to act in an advisory capacity regarding disciplinary matters and trading rules for their respective marketplaces. Under NYSE Arca Rule 3.2(b)(3), which the Exchange proposes to delete, the OTP Advisory Committee is made up of OTP Holders and acts in an advisory capacity regarding rule changes related to disciplinary matters and trading rules. Under NYSE Arca Equities Rule 3.2(b)(3), which the Exchange also proposes to delete, the Member Advisory Committee is made up of ETP Holders and acts in an advisory capacity regarding rule changes related to disciplinary matters and off-board trading rules.

The Exchange proposes that the CFR would serve in the same advisory capacity as the current OTP Advisory and Member Advisory Committees. The Exchange notes that the same categories of permit holders as the advisory committees would be represented on the proposed CFR, whose mandate as set forth in proposed Rule 3.3(a)(2)(A) would include acting in an advisory capacity to the Board with respect to disciplinary matters, the listing and delisting of securities, regulatory programs, rulemaking and regulatory rules, including trading rules. The proposed CFR would therefore serve in the same advisory capacity as the OTP Advisory and Member Advisory Committees. The Exchange accordingly believes that retaining the OTP Advisory Committee or Member Advisory Committee would be redundant and unnecessary. The Exchange notes that the proposal is consistent with the structure recently approved for the NYSE, which abolished its advisory committees and transferred the functions to the newly created NYSE CFR, whose mandate includes acting in an advisory capacity to the Board with respect to disciplinary matters, the listing and delisting of securities, regulatory programs, rulemaking and regulatory rules, including trading rules. The Exchange’s affiliate NYSE MKT has a similar structure in place.<sup>33</sup> The proposal would therefore align the functions and

responsibilities of the Exchange’s CFR with those of its affiliates. Finally, the Exchange believes that member participation on the proposed CFR would be sufficient to provide for the fair representation of members in the administration of the affairs of the Exchange, including rulemaking and the disciplinary process, consistent with Section 6(b)(3) of the Exchange Act.<sup>34</sup>

#### Deletion of References to NYSE Regulation and NYSE Regulation Chief Executive Officer

In connection with the Exchange’s termination of the intercompany RSA pursuant to which NYSE Regulation provided regulatory services to the Exchange,<sup>35</sup> the Exchange proposes to amend NYSE Arca and NYSE Arca Equities Rule 0 and NYSE Arca Equities Rule 5.3(i)(1) to remove references to “NYSE Regulation, Inc.” and “NYSE Regulation.” The Exchange also proposes to amend NYSE Arca Equities Rule 2.100 to replace a reference to “NYSE Regulation, Inc. Chief Executive Officer” with “Chief Regulatory Officer.”

In particular, NYSE Arca Rule 0 (Regulation of the Exchange, OTP Holders and OTP Firms) and NYSE Arca Equities Rule 0 (Regulation of the Exchange and Exchange Trading Permit Holders), which describes the regulatory services agreement between the NYSE and FINRA, would be amended to remove references to “NYSE Regulation, Inc., NYSE Regulation staff or departments”, retaining the existing reference in Rule 0 to Exchange staff, which reference would encompass the Exchange’s regulatory staff.<sup>36</sup>

Similarly, subdivision (i)(1) of NYSE Arca Equities Rule 5.3 (Financial Reports and Related Notices) would be amended to replace the reference to “NYSE Regulation” with “regulatory staff” to more particularly describe who an issuer should consult with under the Rule.

Finally, the Exchange proposes to amend NYSE Arca Equities Rule 2.100 to replace “NYSE Regulation, Inc. Chief Executive Officer” with “Chief Regulatory Officer.” NYSE Arca Equities Rule 2.100 currently provides that, for purposes of the rule,<sup>37</sup> a “qualified

<sup>34</sup> See 15 U.S.C. 78f(b)(3). See also note 26, *supra*.

<sup>35</sup> See note 5, *supra*.

<sup>36</sup> The Exchange also proposes to delete the semicolon at the end of the heading of Rule 0 as unnecessary.

<sup>37</sup> NYSE Arca Equities Rule 2.100 provides that if a qualified Affiliated Exchange (as defined therein) officer declares an emergency condition under that market’s rules, a qualified NYSE Arca Equities officer may authorize NYSE Arca Equities to perform certain functions on behalf of the Affiliated Exchange.

Corporation officer” means the Chief Executive Officer of Intercontinental Exchange, Inc., or his or her designee, or the NYSE Regulation, Inc. Chief Executive Officer or his or her designee. “NYSE Regulation, Inc. Chief Executive Officer” is used in this Rule but CRO or Chief Regulatory Officer is used elsewhere in the Exchange’s rules to designate the same position.<sup>38</sup> In particular, Chief Regulatory Officer is used to designate the individual who can participate or designate participants to various panels, including panels adjudicating clearly erroneous transactions (NYSE Arca Equities 7.10) and ETP Holders disputing an NYSE Arca Equities decision to disapprove or disqualify it from the participating in the Retail Liquidity Program (NYSE Arca Equities Rule 7.44). Chief Regulatory Officer is also used in NYSE Arca’s Rules to designate the individual who can participate or designate participants to panels adjudicating erroneous trades due to system disruptions or malfunctions (NYSE Arca Rule 6.89) and nullification and adjustment of options transactions, including obvious errors (NYSE Arca Rule 6.87). Accordingly, the Exchange proposes to replace references to “NYSE Regulation, Inc. Chief Executive Officer” with “Chief Regulatory Officer” in Rule 2.100.

#### 2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Exchange Act<sup>39</sup> in general, and with Section 6(b)(1)<sup>40</sup> in particular, in that it enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and to comply, and to enforce compliance by its exchange members and persons associated with its exchange members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the Exchange.

The proposal to amend Section 4.01(a) of the NYSE Arca Bylaws and NYSE Arca and NYSE Arca Equities Rules 3.3 to establish a Committee for Review as a sub-committee of the recently approved ROC, and to delete NYSE Arca Rule 3.2(b)(3) governing the OTP Advisory Committee and NYSE Arca Equities Rule 3.2(b)(3) governing the Member Advisory Committee, both of whose functions will be assumed by the Committee for Review, complies with Section 6(b)(7) of the Exchange

<sup>38</sup> See, e.g., NYSE Arca Rules 6.89 & 6.87 and NYSE Arca Equities Rules 7.10 & 7.44.

<sup>39</sup> 15 U.S.C. 78f(b).

<sup>40</sup> 15 U.S.C. 78f(b)(1).

<sup>33</sup> See NYSE Approval Order, 80 FR at 59840 & NYSE MKT Approval Order, 81 FR at 6312.

Act,<sup>41</sup> which requires that the rules of a national securities exchange provide a fair procedure for the disciplining of members and persons associated with members. The members of the Exchange's ROC are all Public Directors of the Exchange Board, thereby ensuring that the ROC is comprised of independent members.<sup>42</sup> The Exchange proposes to retain in the CFR the requirement currently applicable to the Board Appeals Committee that the committee be made up of the OTP Director(s), the ETP Director(s) and the Public Directors of both markets.

Further, the Exchange believes that permitting the CFR to appoint CFR Appeals Panels composed of at least three and no more than five individuals to conduct reviews of matters decided by the EBCC and BCC for the options and equities marketplaces is consistent with Section 6(b)(7) of the Exchange Act. CFR Appeals Panels for NYSE Arca would contain at least one Public Director and at least one Director that is an OTP Holder or Allied Person or Associated Person of an OTP Firm, and CFR Appeals Panels for NYSE Arca Equities would contain at least one Public Director and at least one Director that is an ETP Holder or Allied Person or Associated Person of an ETP Holder. The Exchange believes that the role of the CFR Appeals Panels, including that the CFR would retain authority to determine the disposition of appeals, would ensure that the Exchange's rules provide a fair procedure for the disciplining of members and persons associated with members. In addition, for the reasons stated below, the Exchange believes that participation on the proposed CFR and CFR Appeals Panels of permit holders and persons allied or associated with permit holders would be sufficient to provide for the fair representation of members in the administration of the affairs of the Exchange, including rulemaking and the disciplinary process, consistent with Section 6(b)(3) of the Exchange Act.

The Exchange believes that having the Exchange Board, rather than the board of directors of its subsidiary NYSE Arca Equities, appoint the members of the appeals panel for the equities marketplace complies with Section 6(b)(7) of the Exchange Act. The Exchange is the entity with ultimate legal responsibility for the regulation of its permit holders and markets. As noted, under the proposal, the CFR would consist of the OTP Director(s), the ETP Director(s) and the Public Directors, thereby ensuring that CFR

Appeals Panels named for the equities marketplace would consist of at least one Public Director and at least one director that is an ETP Holder or Allied Person or Associated Person of an ETP Holder.

The Exchange believes that having the CFR serve in the advisory capacity of the OTP Advisory Committee and Member Advisory Committee for the Exchange's options and equities marketplaces, respectively, is consistent with and facilitates a governance and regulatory structure that furthers the objectives of Section 6(b)(5) of the Exchange Act.<sup>43</sup> The Exchange believes that permit holder participation on the proposed CFR would be sufficient to provide for the fair representation of members in the administration of the affairs of the Exchange, including rulemaking and the disciplinary process, consistent with Section 6(b)(3) of the Exchange Act.

The Exchange believes that deleting the reference to the "NYSE Regulation, Inc. Chief Executive Officer" in NYSE Arca Equities Rule 2.100 and replacing it with Chief Regulatory Officer, which is used throughout the Exchange's rules, removes impediments to and perfects a national market system because it would reduce potential confusion that may result from retaining different designations for the same individual in the Exchange's rulebook. Removing potentially confusing conflicting designations would also further the goal of transparency and add consistency to the Exchange's rules.

Finally, making conforming amendments to NYSE Arca Rules 2.4, 10.3, 10.6, 10.8, 10.11, 10.12, 10.14 and NYSE Arca Equities Rules 2.3, 5.5, 10.3, 10.6, 10.8, 10.11, 10.12, and 10.13 in connection with creation of the proposed CFR removes impediments to and perfects the mechanism of a free and open market by removing confusion that may result from having obsolete references in the Exchange's rulebook. Deleting references to "NYSE Regulation, Inc." and "NYSE Regulation" in NYSE Arca and NYSE Arca Equities Rule 0 and NYSE Arca Equities Rule 5.3(i)(1) and references to the "NYSE Arca Board of Governors" in

<sup>43</sup> 15 U.S.C. 78f(b)(5). Section 6(b)(5) of the Exchange Act requires the proposed rules to be consistent with and facilitate a governance and regulatory structure that is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

NYSE Arca Equities Rules 3.3, 10.3, 10.12 and 10.13 removes impediments to and perfects the mechanism of a free and open market by removing confusion that may result from having obsolete references in the Exchange's rulebook. The Exchange further believes that the proposal removes impediments to and perfects the mechanism of a free and open market by ensuring that persons subject to the Exchange's jurisdiction, regulators, and the investing public can more easily navigate and understand the Exchange's rulebook. The Exchange believes that eliminating obsolete references would not be inconsistent with the public interest and the protection of investors because investors will not be harmed and in fact would benefit from increased transparency, thereby reducing potential confusion. Removing such obsolete references will also further the goal of transparency and add clarity to the Exchange's rules.

#### *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 Exchange Act. The proposed rule change is not intended to address competitive issues but rather is concerned solely with the administration and functioning of the Exchange and its board of directors.

#### *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**

Within 45 days of the date of publication of this notice in the **Federal Register** or up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- (A) By order approve or disapprove the proposed rule change, or
- (B) Institute proceedings to determine whether the proposed rule change should be disapproved.

### **IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule

<sup>41</sup> See 15 U.S.C. 78f(b)(7).

<sup>42</sup> See Release No. 75155, 80 FR at 34744.

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](mailto:rule-comments@sec.gov). Please include File Number SR-NYSEArca-2016-11 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-NYSEArca-2016-11. 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 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-2016-11, and should be submitted on or before May 3, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>44</sup>

**Robert W. Errett,**

*Deputy Secretary.*

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**SECURITIES AND EXCHANGE COMMISSION**

[Release No. 34-77537; File No. SR-EDGA-2016-02]

**Self-Regulatory Organizations; EDGA Exchange, Inc.; Order Approving Proposed Rule Change, as Modified by Amendment No. 1 Thereto, To Adopt an Early Trading Session and Three New Time-in-Force Instructions**

April 6, 2016.

**I. Introduction**

On February 2, 2016, EDGA Exchange, Inc. (the "Exchange" or "EDGA") filed with the Securities and Exchange Commission (the "Commission"), pursuant to Section 19(b)(1)<sup>1</sup> of the Securities Exchange Act of 1934 ("Act")<sup>2</sup> and Rule 19b-4 thereunder,<sup>3</sup> a proposed rule change to amend its rules to: (i) Create a new trading session to be known as the Early Trading Session, which will run from 7:00 a.m. to 8:00 a.m. Eastern Time; and (ii) adopt three new Time-in-Force ("TIF") instructions. On February 12, 2016, the Exchange filed Amendment No. 1 to the proposed rule change.<sup>4</sup> The proposed rule change, as modified by Amendment No. 1 thereto, was published for comment in the **Federal Register** on February 22, 2016.<sup>5</sup> The Commission received no comments on the proposed rule change. This order approves the proposed rule change, as modified by Amendment No. 1.

**II. Description of the Proposal**

The Exchange proposes to amend its rules to: (i) Create a new trading session, the Early Trading Session, which will run from 7:00 a.m. to 8:00 a.m. Eastern Time; and (ii) adopt three new TIF instructions.<sup>6</sup>

*A. Early Trading Session*

The Exchange trading day is currently divided into three sessions: (i) The Pre-Opening Session which starts at 8:00 a.m. and ends at 9:30 a.m. Eastern Time; (ii) Regular Trading Hours which runs from 9:30 a.m. to 4:00 p.m. Eastern Time; and (iii) the Post-Closing Session, which runs from 4:00 p.m. to 8:00 p.m.

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 15 U.S.C. 78a.

<sup>3</sup> 17 CFR 240.19b-4.

<sup>4</sup> In Amendment No. 1, the Exchange noted that it would subject orders that are eligible for execution at the start of the Pre-Opening Session to all of the Exchange's standard regulatory checks, including compliance with Regulation NMS, Regulation SHO as well as other relevant Exchange rules.

<sup>5</sup> See Securities Exchange Act Release No. 77141 (February 16, 2016), 81 FR 8797 ("Notice").

<sup>6</sup> See Notice, *supra* note 5.

Eastern Time. The Exchange proposes to amend its rules to create the Early Trading Session. Exchange Rule 1.5 would be amended to add a new term, "Early Trading Session," under proposed paragraph (ii). "Early Trading Session" would be defined as "the time between 7:00 a.m. and 8:00 a.m. Eastern Time."

The Exchange also proposes to amend Exchange Rule 11.1(a) to state that orders may be entered or executed on, or routed away from, the Exchange during the the Early Trading Session and to reflect the start time of the Early Trading Session as 7:00 a.m. Eastern Time. Other than the proposal to adopt an Early Trading Session, the Exchange does not propose to amend the substance or operation of Exchange Rule 11.1(a).<sup>7</sup>

Users<sup>8</sup> currently designate when their orders are eligible for execution by selecting a desired TIF instruction.<sup>9</sup> Orders entered between 6:00 a.m. and 8:00 a.m. Eastern Time are not eligible for execution until the start of the Pre-Opening Session or Regular Trading Hours, depending on the TIF selected by the User. Users may enter orders in advance of the trading session for which the order is eligible. For example, Users may enter orders starting at 6:00 a.m. Eastern Time with a TIF of Regular Hours Only ("RHO"), which designates that the order only be eligible for execution during Regular Trading Hours.<sup>10</sup> Users may enter orders as early as 6:00 a.m. Eastern Time, but those orders would not be eligible for execution until the start of the Pre-Opening Session at 8:00 a.m. According to the Exchange, some Users have requested the ability for their orders to be eligible for execution starting at 7:00 a.m. Eastern Time. Therefore, the Exchange is proposing to adopt the Early Trading Session.<sup>11</sup>

As amended, Exchange Rule 11.1(a)(1) would state that orders entered between 6:00 a.m. and 7:00 a.m. Eastern Time, rather than 6:00 a.m. and 8:00 a.m. Eastern Time, would not be eligible for execution until the start of the Early Trading Session, Pre-Opening Session, or Regular Trading Hours, depending on the TIF selected by the User. Exchange Rule 11.1(a)(1) will also be amended to state that the Exchange will not accept the following orders prior to 7:00 a.m. Eastern Time, rather than 8:00 a.m.:

<sup>7</sup> See *id.* at 8798.

<sup>8</sup> "User" is defined as "any Member or Sponsored Participant who is authorized to obtain access to the System pursuant to Rule 11.3." See Exchange Rule 1.5(ee).

<sup>9</sup> See Exchange Rule 11.6(q).

<sup>10</sup> See Exchange Rule 11.6(q)(6).

<sup>11</sup> See Notice, *supra* note 5, at 8798.

<sup>44</sup> 17 CFR 200.30-3(a)(12).

Orders with a Post Only instruction,<sup>12</sup> Intermarket Sweep Orders (“ISOs”),<sup>13</sup> Market Orders<sup>14</sup> with a TIF other than Regular Hours Only, orders with a Minimum Execution Quantity instruction<sup>15</sup> that also include a TIF of Regular Hours Only, and all orders with a TIF instruction of Immediate-or-Cancel (“IOC”)<sup>16</sup> or Fill-or-Kill (“FOK”).<sup>17</sup> At the commencement of the Early Trading Session, orders entered between 6:00 a.m. and 7:00 a.m. Eastern Time, rather than 6:00 a.m. and 8:00 a.m. Eastern Time, will be handled in time sequence, beginning with the order with the oldest time stamp, and will be placed on the EDGA Book,<sup>18</sup> routed, cancelled, or executed in accordance with the terms of the order. As amended, Exchange Rule 11.1(a) would state that orders may be executed on the Exchange or routed away from the Exchange during Regular Trading Hours and during the Early Trading, Pre-Opening, Regular and Post Closing Sessions.<sup>19</sup>

The Exchange also proposes to make the changes described below to Exchange Rules 3.21, 11.8, 11.10, 11.15, 14.1, 14.2 and 14.3 to reflect the adoption of the Early Trading Session:

- Exchange Rule 3.21, Customer Disclosures. Exchange Rule 3.21 prohibits Members from accepting an order from a customer for execution in the Pre-Opening or Post-Closing Session without disclosing to their customer that extended hours trading involves material trading risks, including the possibility of lower liquidity, high volatility, changing prices, unlinked markets, an exaggerated effect from news announcements, wider spreads and any other relevant risk. The Exchange proposes to amend Exchange Rule 3.21 to also require such disclosures for customer orders that are to be executed during the Early Trading Session.

- Exchange Rules 11.8(b), (c), (d), (e) and (g). The Exchange proposes to amend the description of Limit Orders under Exchange Rule 11.8(b), ISOs

under Exchange Rule 11.8(c), MidPoint Peg Orders under Exchange Rule 11.8(d), MidPoint Discretionary Orders (“MDO”) under Rule 11.8(e), and Supplemental Peg Orders under Rule 11.8(g) to account for the Early Trading Session. Every order type that is currently available beginning at 8:00 a.m. will be available beginning at 7:00 a.m. for inclusion in the Early Trading Session. All other order types, and all order type behaviors, will otherwise remain unchanged. Therefore, each of the above rules for Limit Orders, ISOs, MidPoint Peg Orders, MDOs, and Supplemental Peg Orders would be amended to state that those order types are available during the Early Trading Session.

- Exchange Rules 11.8(a) and (f). Market Orders and Market Maker Peg Orders would not be eligible for execution during the Early Trading Session. Market Orders are only eligible for execution during the Regular Session.<sup>20</sup> Market Maker Peg Orders may currently be submitted to the Exchange starting at the beginning of the Pre-Opening Session, but the order will not be executable or automatically priced until after the first regular way transaction on the listing exchange in the security, as reported by the responsible single plan processor. Exchange Rule 11.8(f)(7) would be amended to state that Market Maker Peg Orders may be submitted to the Exchange starting at the beginning of the Early Trading Session. Market Maker Peg Orders would continue to not be executable or automatically priced until after the first regular way transaction on the listing exchange in the security, as reported by the responsible single plan processor.

- Exchange Rule 11.10, Order Execution and Routing. Exchange Rule 11.10(a)(2) discusses compliance with Regulation NMS and Trade Through Protections and states that the price of any execution occurring during the Pre-Opening Session or the Post-Closing Session must be equal to or better than the highest Protected Bid or lowest Protected Offer, unless the order is marked ISO or a Protected Bid is crossing a Protected Offer. The Exchange proposes to amend Exchange Rule 11.10(a)(2) to expand the rule’s requirements to the Early Trading Session.

- Exchange Rule 11.15, Clearly Erroneous Executions. Exchange Rule 11.15 outlines under which conditions the Exchange may determine that an execution is clearly erroneous. The Exchange proposes to amend Exchange

Rule 11.15 to include executions that occur during the Early Trading Session. Exchange Rule 11.15(c)(1) sets forth the numerical guidelines the Exchange is to follow when determining whether an execution was clearly erroneous during Regular Trading Hours or the Pre-Opening or Post-Closing Trading Session. Exchange Rule 11.15(c)(3) sets forth additional factors the Exchange may consider in determining whether a transaction is clearly erroneous. These factors include whether the transaction was executed during the Pre-Opening or Post-Closing Trading Sessions. The Exchange proposes to amend Exchange Rule 11.15(c)(1) and (3) to include executions occurring during the Early Trading Session.

- Exchange Rule 14.1, Unlisted Trading Privileges. The Exchange proposes to amend Exchange Rules 14.1(c)(2), and Interpretation and Policies .01(a) and (b) to account for the Early Trading Session. Specifically, the Exchange proposes to amend paragraph (c)(2) to state that an information circular distributed by the Exchange prior to the commencement of trading of a UTP Derivative Security<sup>21</sup> will describe the risk of trading during the Early Trading Session.<sup>22</sup> In addition, the Exchange proposes to amend Interpretation and Policies .01(a) to add Early Trading Session to the paragraph’s title and to state that if a UTP Derivative Security begins trading on the Exchange in the Early Trading Session or Pre-Opening Session and subsequently a temporary interruption occurs in the calculation or wide dissemination of the Intraday Indicative Value (“IIV”) or the value of the underlying index, as applicable, to such UTP Derivative Security, by a major market data vendor, the Exchange may continue to trade the UTP Derivative Security for the remainder of the Early Trading Session and Pre-Opening Session. Lastly, the Exchange proposes to amend Interpretation and Policies .01(b) to add Early Trading Session to the paragraph’s title and to amend subparagraph (2) of that section to state that if the IIV or the value of the underlying index continues not to be calculated or widely available as of the commencement of the Early Trading Session or Pre-Opening Session on the next business day, the Exchange shall not commence trading of the UTP Derivative Security in the Early Trading Session or Pre-Opening Session that day.

<sup>21</sup> See Exchange Rule 14.1(c).

<sup>22</sup> Currently, the information circular describes only those risks in the Pre-Opening and Post-Closing Trading Sessions.

<sup>12</sup> See Exchange Rule 11.6(n)(4).

<sup>13</sup> See Exchange Rule 11.8(c).

<sup>14</sup> See Exchange Rule 11.8(a).

<sup>15</sup> See Exchange Rule 11.6(h).

<sup>16</sup> See Exchange Rule 11.6(q)(1).

<sup>17</sup> See Exchange Rule 11.6(q)(3).

<sup>18</sup> See Exchange Rule 1.5(d).

<sup>19</sup> The Exchange also describes how the Early Trading Session will affect its Members’ operations and the Exchange’s opening process, order types, routing services, order processing, data feeds, trade reporting, market surveillance, and clearly erroneous trade processing. The Exchange clarifies that these processes will operate in the same manner with the exception of changes in time to reflect the adoption of the Early Trading Session. See Notice, *supra* note 5, at 8798–99.

<sup>20</sup> See Exchange Rule 11.8(a)(5).

- Exchange Rule 14.2, Investment Company Units. The Exchange proposes to amend Exchange Rule 14.2(g) to state that transactions in Investment Company Units may occur during the Early Trading Session. Currently, such transactions may occur during Regular Trading Hours and the Pre-Opening and Post Closing Sessions.

- Exchange Rule 14.3, Trust Issued Receipts. The Exchange proposes to amend Exchange Rule 14.3(d) to state that transactions in Trust Issued Receipts may occur during the Early Trading Session. Currently, such transactions may occur during Regular Trading Hours and the Pre-Opening and Post-Closing Sessions.

### B. TIF Instructions

The Exchange proposes to adopt three new TIF instructions under Exchange Rule 11.6(q).<sup>23</sup> As discussed above, a User may designate when its order is eligible for execution by selecting the desired TIF instruction under Exchange Rule 11.6(q).<sup>24</sup>

Although the Exchange states that the proposal to adopt an Early Trading Session is in response to User requests for their orders to be eligible for execution starting at 7:00 a.m. Eastern Time, some Users have requested that their orders continue to not be eligible for execution until the start of the Pre-Opening Session at 8:00 a.m.<sup>25</sup> Therefore, the Exchange proposes to adopt the following three new TIF instructions under Exchange Rule 11.6(q):

- Pre-Opening Session Plus (“PRE”). A limit order that is designated for execution during the Pre-Opening Session and Regular Trading Hours. Like the current Day TIF instruction,<sup>26</sup> any portion not executed expires at the end of Regular Trading Hours.

- Pre-Opening Session ‘til Extended Day (“PTX”). A limit order that is designated for execution during the Pre-Opening Session, Regular Trading Hours, and the Post-Closing Session. Like the current GTX TIF instruction,<sup>27</sup> any portion not executed expires at the end of the Post-Closing Session.

- Pre-Opening Session ‘til Day (“PTD”). A limit order that is designated for execution during the Pre-Opening

Session, Regular Trading Hours, and the Post-Closing Session. Like the current GTD TIF instruction,<sup>28</sup> any portion not executed will be cancelled at the expiration time assigned to the order, which can be no later than the close of the Post-Closing Trading Session.

Under each proposed TIF instruction, Users may designate that their orders only be eligible for execution starting with the Pre-Opening Session. Users may continue to enter orders as early as 6:00 a.m., but orders with the proposed TIF instructions would not be eligible for execution until 8:00 a.m. Eastern Time, the start of the Pre-Opening Session.<sup>29</sup> At the commencement of the Pre-Opening Session, orders entered between 6:00 a.m. and 8:00 a.m. Eastern Time with one of the proposed TIF instructions will be handled in time sequence, beginning with the order with the oldest time stamp, and will be placed on the EDGA Book, routed, cancelled, or executed in accordance with the terms of the order.<sup>30</sup>

The Exchange proposes to amend the following order types under Exchange Rule 11.8 to account for the three proposed TIF instructions:

- Market Orders. The proposed TIF instruction of PRE, PTX, and PTD would not be available for Market Orders. Under Exchange Rule 11.8(a)(2), a Market Order may only include a TIF instruction of IOC, RHO, FOK, or Day.

- Limit Orders. Exchange Rule 11.8(b)(2) describes the TIF instructions that may be attached to a Limit Order. The Exchange proposes to amend paragraph (b)(2) to add the TIF instructions of PRE, PTX, or PTD to the list of TIF instructions that a Limit Order may include.

- ISOs. Exchange Rule 11.8(c)(1) describes the TIF instructions that may be attached to an incoming ISO. The Exchange proposes to amend paragraph (c)(1) to state that an incoming ISO may have a TIF instruction of PRE, PTX, or PTD, in addition to Day, GTD, RHO, GTX, and IOC. Exchange Rule 11.8(c)(1) would be further amended to state that an incoming ISO with a Post Only and TIF instruction of PRE, PTX, or PTD, like those with an TIF instruction or GTD, GTX, or Day, will be cancelled without execution if, when entered, it is immediately marketable against an order with a Displayed instruction resting in the EDGA Book unless such

order removes liquidity pursuant to Exchange Rule 11.6(n)(4).<sup>31</sup>

- MidPoint Peg Orders. Exchange Rule 11.8(d)(1) describes the TIF instructions that may be attached to a MidPoint Peg Order. The Exchange proposes to amend paragraph (d)(1) to state that a MidPoint Peg Order may have a TIF instruction of PRE, PTX, or PTD, in addition to Day, FOK, IOC, RHO, GTX and GTD.

- MDO. Rule 11.8(e)(1) describes the TIF instructions that may be attached to an MDO. The Exchange proposes to amend paragraph (e)(1) to state that an MDO may have a TIF instruction of PRE, PTX, or PTD, in addition to Day, RHO, GTX and GTD.

- Market Maker Peg Orders. The proposed TIF instruction of PRE, PTX, and PTD would not be available to Market Maker Peg Orders. Under Exchange Rule 11.8(f)(4), a Market Maker Peg Order may only include a TIF instruction of Day, RHO, or GTD.

- Supplemental Peg. Exchange Rule 11.8(g)(1) describes the TIF instructions that may be attached to a Supplemental Peg Order. The Exchange proposes to amend paragraph (g)(1) to state that a Supplemental Peg Order may have a TIF instruction of PRE, PTX, or PTD, in addition to GTD, GTX, RHO and Day.

### III. Discussion and Commission Findings

After careful consideration, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.<sup>32</sup> The Commission believes that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5)<sup>33</sup> in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the

<sup>23</sup> The Exchange also proposes to amend the descriptions of Good-‘til Day (“GTD”) under Exchange Rule 11.6(q)(4) and Good-‘til Extended Day (“GTX”) under Exchange Rule 11.6(q)(5) to replace incorrect references to the Post-Market Session with Post-Closing Session, as Post-Closing Session is the accurate term under Exchange Rule 11.5(r).

<sup>24</sup> See Exchange Rule 11.1(a)(1).

<sup>25</sup> See Notice, *supra* note 5, at 8800.

<sup>26</sup> See Exchange Rule 11.6(q)(2).

<sup>27</sup> See Exchange Rule 11.6(q)(5).

<sup>28</sup> See Exchange Rule 11.6(q)(4).

<sup>29</sup> Orders utilizing one of the proposed TIF instructions would not be eligible for execution during the Early Trading Session.

<sup>30</sup> See Exchange Rule 11.1(a).

<sup>31</sup> Exchange Rule 11.6(n)(4) defines the Post Only instruction and states, in sum, that an order with a Post Only instruction and a Display-Price Sliding or Price Adjust instruction will remove contra-side liquidity from the EDGA Book if the order is an order to buy or sell a security priced below \$1.00 or if the value of such execution when removing liquidity equals or exceeds the value of such execution if the order instead posted to the EDGA Book and subsequently provided liquidity, including the applicable fees charged or rebates provided.

<sup>32</sup> In approving this rule change, the Commission notes that it has considered the proposed rule’s impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

<sup>33</sup> 15 U.S.C. 78f(b)(5).

mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange proposes to adopt an Early Trading Session and three new TIF instructions and to make related changes to its rules as discussed above.<sup>34</sup> The Commission believes that the proposed rules would provide Users with additional options for trading on the Exchange. The Commission notes that the proposed Early Trading Session hours are similar to those of other exchanges<sup>35</sup> and that the proposed TIF instructions would offer functionality similar to existing functionality available on the Exchange and other exchanges which allows Members to select when their orders become eligible for execution.<sup>36</sup>

The Commission notes that the Exchange has represented that it would subject orders that are eligible for execution as of the start of the Pre-Opening Session to all of the Exchange's standard regulatory checks, as it currently does with all orders upon entry.<sup>37</sup> Specifically, the Exchange will subject such orders to checks for compliance with, including but not limited to, Regulation NMS,<sup>38</sup> Regulation SHO,<sup>39</sup> and relevant Exchange rules. Moreover, the Exchange reminds its Members of their regulatory obligations when submitting an order with one of the proposed TIF instructions.<sup>40</sup> In particular, the Exchange states that Members must comply with the Market Access Rule,<sup>41</sup> which requires, among other things, pre-trade controls and procedures that are reasonably designed to assure compliance with Exchange trading rules and Commission rules pursuant to Regulation SHO and Regulation NMS. The Exchange also notes that a Member's procedures must be

reasonably designed to ensure compliance with the applicable regulatory requirements, not just at the time the order is routed to the Exchange, but also at the time the order becomes eligible for execution.<sup>42</sup>

The Commission further notes the Exchange's discussion of the best execution obligations of Members utilizing the proposed TIF instructions.<sup>43</sup> Specifically, the Exchange states that a Member's best execution obligations may include cancelling an order when market conditions deteriorate and could result in an inferior execution or informing customers if the execution of their order may be delayed intentionally while the Member utilizes reasonable diligence to ascertain the best market for the security.<sup>44</sup> The Exchange further notes that Members will maintain the ability to cancel or modify the terms of an order utilizing any of the proposed TIF instructions at any time, including during the time from when the order is routed to the Exchange until the start of the Pre-Opening Session. As a result, the Exchange states that a Member who utilizes the proposed TIF instructions, but later determines that market conditions favor execution during the Early Trading Session, can cancel the order residing at the Exchange and enter a separate order to execute during the Early Trading Session.<sup>45</sup>

#### IV. Conclusion

*It is therefore ordered*, pursuant to Section 19(b)(2) of the Act<sup>46</sup> that the proposed rule change (SR-EDGA-2016-02), as modified by Amendment No. 1, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>47</sup>

**Robert W. Errett,**  
*Deputy Secretary.*

[FR Doc. 2016-08301 Filed 4-11-16; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-77540; File No. SR-NYSEMKT-2016-42]

### Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing of Proposed Rule Change To Amend Rule 952NY With Respect to Opening Trading in an Options Series

April 6, 2016.

Pursuant to Section 19(b)(1)<sup>1</sup> of the Securities Exchange Act of 1934 (the "Act")<sup>2</sup> and Rule 19b-4 thereunder,<sup>3</sup> notice is hereby given that, on March 23, 2016, NYSE MKT LLC (the "Exchange" or "NYSE MKT") 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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 952NY (Opening Process) with respect to opening trading in an options series. The proposed rule change is available on the Exchange's Web site at [www.nyse.com](http://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 Exchange is proposing changes to Rule 952NY with respect to opening

<sup>34</sup> See *supra* section II.

<sup>35</sup> For example, NYSE Arca, Inc. operates an Opening Session that starts at 4:00 a.m. Eastern Time and ends at 9:30 a.m. Eastern Time and Nasdaq Stock Market LLC operates a pre-market session that also opens at 4:00 a.m. and ends at 9:30 a.m. Eastern Time. See NYSE Arca Rule 7.34(a)(1); Nasdaq Rule 4701(g); see also Securities Exchange Act Release No. 60605 (September 1, 2009), 74 FR 46277 (September 8, 2009) (SR-CHX-2009-13) (adopting bifurcated post-trading session on the Chicago Stock Exchange, Inc.).

<sup>36</sup> Specifically, on the Exchange, Users may enter an order starting at 6:00 a.m. Eastern Time with a TIF of Regular Hours Only, which designates that the order only be eligible for execution during Regular Trading Hours, which begin at 9:30 a.m. Eastern Time. See Exchange Rule 11.6(q)(6); see also NASDAQ Rule 4703(a)(7).

<sup>37</sup> See Amendment No. 1, *supra* note 4.

<sup>38</sup> See 17 CFR 242.600-613.

<sup>39</sup> See 17 CFR 242.200-204.

<sup>40</sup> See Notice, *supra* note 5, at 8802.

<sup>41</sup> See 17 CFR 240.15c3-5.

<sup>42</sup> See Notice, *supra* note 5, at 8802.

<sup>43</sup> See *id.* at 8801-02.

<sup>44</sup> *Id.* at 8802 n.45.

<sup>45</sup> *Id.* at 8801.

<sup>46</sup> 15 U.S.C. 78s(b)(2).

<sup>47</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C.78s(b)(1).

<sup>2</sup> 15 U.S.C. 78a.

<sup>3</sup> 17 CFR 240.19b-4.

trading in an option series as described below.

#### Opening Process

Rule 952NY describes the process pursuant to which the System<sup>4</sup> opens an option series. Paragraphs (b) and (c) of Rule 952NY provide that, after the primary market for the underlying security disseminates the opening trade or opening quote, the System then conducts an “Auction Process” to open a series whereby the System determines a single price at which a series may be opened by looking to: (i) The midpoint of the initial uncrossed NBBO disseminated by the Options Price Reporting Authority (“OPRA”), if any, or (ii) the midpoint of the best quotes or orders in the System Book. If the bid-ask differential for a series is not within an acceptable range, the System will not conduct an Auction Process.<sup>5</sup> For purposes of this rule, the acceptable range means the bid-ask differential guidelines specified in Rule 925NY(b)(4).<sup>6</sup> Assuming the bid-ask differential is within the acceptable range, the System matches up orders and quotes based on price-time priority<sup>7</sup> and executes the orders that are matched at the midpoint pricing.<sup>8</sup>

Any orders in the System that are not executed in the Auction Process become eligible for the Core Trading Session immediately after the conclusion of the Auction Process. If the System does not open a series with an Auction Process, the System shall open the series for trading after receiving notification of an initial NBBO disseminated by OPRA for the series or on a Market Maker quote, provided that the bid-ask differential does not exceed the bid-ask differential specified under Rule 925NY(b)(5).<sup>9</sup>

<sup>4</sup> The term “System” refers to the Exchange’s electronic order delivery, execution and reporting system through which orders and quotes for listed options are consolidated for execution and/or display. See Rule 900.2NY(48) (defining “Exchange System” or “System”).

<sup>5</sup> The Auction bid-ask differentials are known in common parlance as “legal-width quotes.”

<sup>6</sup> See Rule 925NY(b)(4). The bid-ask guidelines specified in Rule 925NY(b)(4) that are required to open a series are narrower than the \$5 wide bid-ask differential for options traded on the System during Core Trading Hours.

<sup>7</sup> Orders will have priority over Market Maker quotes at the same price. See Rule 952NY(b)(B).

<sup>8</sup> See Rule 952NY(b)(B). The Exchange notes that the word Order appears capitalized in this paragraph and, because it is not a defined term, the Exchange proposes the non-substantive change of eliminating the capitalization.

<sup>9</sup> See Rule 925NY(b)(5). Rule 925NY(b)(5) provides that options traded on the System during Core Trading Hours may be quoted with a difference not to exceed \$5 between the bid and offer regardless of the price of the bid.

#### Proposed Modifications to the Opening Process

First, the Exchange proposes to change Rule 952NY(b) regarding how the System determines when to start the Auction Process. Current paragraph (b) of the Rule provides that “[a]fter the primary market for the underlying security disseminates the opening trade or the opening quote, the related option series will be opened automatically.” However, because it is possible that either an opening quote or opening trade alone may not accurately reflect the state of the market, the Exchange proposes to specify that an option series will be opened automatically, “once the primary market for the underlying security disseminates a quote and a trade that is at or within the quote.”<sup>10</sup> The Exchange believes the proposed change makes clear that the Exchange would only open a series automatically after it receives a quote in the underlying security and a trade in that security at or between the disseminated quote rather than simply upon receipt of either an “opening trade or opening quote.” The Exchange believes that waiting to open trading in an option series until there has been both a disseminated quote and trade in the underlying security would help to augment the Auction Process by ensuring that an underlying security has been opened pursuant to a robust price discovery process before opening the overlying options for trading. The Exchange believes that the proposed change would provide market participants with greater certainty as to the true state of the market at the opening of the trading day and should lead to more accurate prices on the Exchange.<sup>11</sup>

Next, the Exchange proposes to modify Rule 952NY(b)(E), which currently provides, in relevant part, that “[i]f the System does not open a series with an Auction Process, the System shall open the series for trading after receiving notification of an initial NBBO disseminated by OPRA for the series or on a Market Maker quote.”<sup>12</sup> However, the Exchange has determined that it would no longer open on a local Market Maker quote but would require that

<sup>10</sup> See proposed Rule 952NY(b). The Exchange also proposes to clarify that “[a]t or after 9:30 a.m. Eastern Time,” *i.e.*, when the market opens, the Exchange would initiate the Opening Process for all series associated with the underlying security. See *id.*

<sup>11</sup> The Exchange notes that it would not open, for example if the first disseminated quote in the underlying security is \$50.50 bid, \$50.75 ask, and the first trade in the underlying had been executed for \$50.00. The Exchange would, however open if the first trade in the underlying was \$50.50.

<sup>12</sup> See Rule 952NY(b)(E).

Market Maker quotes, like the NBBO, come from OPRA. Thus, the Exchange proposes to open after receiving an “initial uncrossed NBBO from ORRA” and to delete rule text related to opening on a Market Maker quote.<sup>13</sup> The Exchange notes that OPRA disseminates to each exchange the NBBO as well as the top of book for each exchange, such that the Exchange’s market maker quote would be disseminated back to the Exchange as the BBO—and could be, but is not necessarily, the NBBO. Because OPRA disseminates this information to all exchanges at the same time, the Exchange believes the proposal to open only after receiving an uncrossed NBBO from OPRA would eliminate any ambiguity as to the source of the information used to open each series and should lead to more accurate prices on the Exchange.

In connection with the proposed changes to Rule 952NY(b), the Exchange likewise proposes to strike from Rule 952NY(c) reference to “the midpoint of the best quote bids and quote offers in the System Book” as it relates to the Exchange determining the opening price for options issues designated for trading on the System.<sup>14</sup> The Exchange believes this conforming change is necessary given that the Exchange would no longer open solely on a Market Maker quote and therefore this information would not form the basis of the opening price of a series. As proposed, the opening price of a series would be the price “at which the greatest number of contracts will trade at or nearest to the midpoint of the initial uncrossed NBBO disseminated by OPRA.”<sup>15</sup> The Exchange believes this change adds transparency and internal consistency to the rule text.

Finally, the Exchange proposes new paragraph (F) to Rule 952NY(c) to provide the Exchange with discretion to deviate from the standard Opening Process where it is necessary in the interests of a fair and orderly market.<sup>16</sup>

<sup>13</sup> See proposed Rule 952NY(b)(E) (providing that “[i]f the System does not open a series with an Auction Process, the System shall open the series for trading after receiving notification of an initial uncrossed NBBO disseminated by OPRA for the series, provided that the bid-ask differential does not exceed the bid-ask differential specified under Rule 925NY(b)(5).”

<sup>14</sup> Current Rule 952NY(c) provides, in relevant part, that the opening price of a series will be the price “at which the greatest number of contracts will trade at or nearest to the midpoint of the initial uncrossed NBBO disseminated by OPRA, if any, or the midpoint of the best quote bids and quote offers in the System Book.”

<sup>15</sup> See proposed Rule 952NY(c).

<sup>16</sup> See proposed Rule 952NY(b)(F) (providing that “[t]he Exchange may deviate from the standard manner of the Auction Process, including adjusting the timing of the Auction Process in any option

This proposed rule change is based on the rules of other options exchanges.<sup>17</sup> Similar to how other markets operate, the Exchange believes it may be appropriate, in the interest of a fair and orderly market, to open trading even if the conditions specified in Rule 952NY(b) are not met. For example, if the primary market is unable to open due to a systems or technical issue, but trading in the underlying security is otherwise unaffected, the Exchange believes it would be appropriate to open trading in any options series overlying such securities. Further, proposed Rule 952NY(b)(F) would provide the Exchange with discretion to manage the Opening Process in the event of unanticipated circumstances occurring around 9:30 a.m. Eastern Time or a halt being lifted.

## 2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b)<sup>18</sup> of the Securities Exchange Act of 1934 (the “Act”), in general, and furthers the objectives of Section 6(b)(5),<sup>19</sup> in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

Specifically, the proposed change to Rule 952NY(b) would clarify that the Exchange would only open a series automatically after it receives a quote in the underlying security and a trade in that security at or between the disseminated quote—as opposed to automatically opening on either an opening quote or an opening trade alone per the current rule text, which may not always accurately reflect the state of the market. The Exchange believes this added transparency would promote just and equitable principles of trade and remove impediments to, and perfect the mechanism of, a free and open market and a national market system to the benefit of market participants. Further, the Exchange believes that waiting to open trading in an option series until there has been both a disseminated quote and trade in the underlying

security would protect investors and the public interest because it would help to augment the Auction Process by ensuring that an underlying security has been opened pursuant to a robust price discovery process before opening the overlying options for trading. Moreover, this proposed change would promote just and equitable principles of trade to the benefit of investors and the public interest because it would provide market participants with greater certainty as to the true state of the market at the opening of the trading day and should lead to more accurate prices on the Exchange.

The Exchange also believes that specifying that, to open a series, the Exchange would require an initial uncrossed NBBO disseminated by OPRA would promote just and equitable principles of trade as the change is designed to protect investors and the public interest. The Exchange notes that OPRA disseminates to each exchange the NBBO as well as the top of book for each exchange, such that the Exchange’s market maker quote would be disseminated back to the Exchange as the BBO—and could be, but is not necessarily, the NBBO. Because OPRA disseminates this information to all exchanges at the same time, the Exchange believes the proposal to open only after receiving an uncrossed NBBO from OPRA would eliminate any ambiguity as to the source of the information for each series and should lead to more accurate prices on the Exchange.

Similarly, the Exchange believes the conforming change to Rule 952NY(c), which strikes reference to quote bids and quote offers in the OX Book [sic] for purposes of determining an opening price, likewise would promote just and equitable principles of trade as it would add transparency and internal consistency to Exchange rules, which would make them easier for market participants to navigate.

Finally, the Exchange believes the proposal to permit the Exchange to open options trading when such opening is in the interests of a fair and orderly market (even if the conditions set forth in the rule are not met), is consistent with the protection of investors and the public interest because the proposed changes would allow the Exchange to open trading in options contracts in a fair and orderly manner. Specifically, the Exchange believes that the proposed changes would reduce potential delays in opening an option series that may prevent the Exchange from displaying and/or routing orders on its Consolidated Book and may also prevent the Exchange from

disseminating a protected quote that draws trading interest from other options markets. Thus, the Exchange believes that the proposed changes would allow the Exchange to open options series faster and more efficiently, thereby reducing any delay in execution of orders on the Exchange that may be unnecessary and harmful to market participants. The Exchange also notes that this proposed rule change is based on the rules of other options exchanges.<sup>20</sup>

## B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue but rather to add specificity and transparency to Exchange rules, thereby reducing confusion and making the Exchange’s rules easier to understand and navigate. The Exchange believes that the proposed rule change would serve to promote regulatory clarity and consistency, thereby reducing burdens on the marketplace and facilitating investor protection.

## 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

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- (A) By order approve or disapprove the proposed rule change, or
- (B) institute proceedings to determine whether the proposed rule change should be disapproved.

## IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.

class, when it believes it is necessary in the interests of a fair and orderly market”).

<sup>17</sup> See e.g., BATS Exchange, Inc. (“BATS”) Rule 21.7(c) (Market Opening Procedures) (“The Exchange may deviate from the standard manner of the Opening Process, including adjusting the timing of the Opening Process in any option class, when it believes it is necessary in the interests of a fair and orderly market”).

<sup>18</sup> 15 U.S.C. 78f(b).

<sup>19</sup> 15 U.S.C. 78f(b)(5).

<sup>20</sup> See *supra* n. 17.



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](mailto:rule-comments@sec.gov). Please include File Number SR-NYSEMKT-2016-42 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-NYSEMKT-2016-42. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEMKT-2016-42 and should be submitted on or before May 3, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>21</sup>

**Robert W. Errett,**

*Deputy Secretary.*

[FR Doc. 2016-08304 Filed 4-11-16; 8:45 am]

**BILLING CODE 8011-01-P**

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-77548; File No. SR-NASDAQ-2015-161]

### Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Order Granting Approval of Proposed Rule Change, as Modified by Amendment Nos. 1, 2, and 3 Thereto, Relating to the Listing and Trading of the Shares of the First Trust RiverFront Dynamic Europe ETF, First Trust RiverFront Dynamic Asia Pacific ETF, First Trust RiverFront Dynamic Emerging Markets ETF, and First Trust RiverFront Dynamic Developed International ETF of First Trust Exchange-Traded Fund III

April 6, 2016.

#### I. Introduction

On December 22, 2015, The NASDAQ Stock Market LLC ("Exchange" or "Nasdaq") filed with the Securities and Exchange Commission ("Commission"), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act" or "Exchange Act")<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> a proposed rule change to list and trade the shares of the First Trust RiverFront Dynamic Europe ETF ("Europe Fund"); First Trust RiverFront Dynamic Asia Pacific ETF ("Asia Pacific Fund"); First Trust RiverFront Dynamic Emerging Markets ETF ("Emerging Markets Fund"); and First Trust RiverFront Dynamic Developed International ETF ("Developed International Fund"). The proposed rule change was published for comment in the **Federal Register** on January 8, 2016.<sup>3</sup> On January 8, 2016, the Exchange filed Amendment No. 1 to the proposed rule change.<sup>4</sup> On February 18, 2016, the Exchange filed Amendment No. 2 to the proposed rule change.<sup>5</sup> On February 19,

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> See Securities Exchange Act Release No. 76817 (January 4, 2016), 81 FR 978 ("Notice").

<sup>4</sup> In Amendment No. 1, the Exchange clarified the proposed rule change by providing additional information regarding the currencies, and instruments that provide exposure to such currencies, in which each Fund will invest. Because Amendment No. 1 to the proposed rule change does not materially alter the substance of the proposed rule change or raise novel regulatory issues, Amendment No. 1 is not subject to notice and comment (Amendment No. 1 is available at: <http://www.sec.gov/comments/sr-nasdaq-2015-161/nasdaq2015161-1.pdf>).

<sup>5</sup> In Amendment No. 2, the Exchange expanded the application of the Alternative Criteria (as discussed below) so that they will apply on a continual basis. Because Amendment No. 2 does not materially alter the substance of the proposed rule change or raise novel regulatory issues, Amendment No. 2 is not subject to notice and comment (Amendment No. 2 is available at: <http://www.sec.gov/comments/sr-nasdaq-2015-161/nasdaq2015161-2.pdf>).

2016, pursuant to Section 19(b)(2) of the Act,<sup>6</sup> the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.<sup>7</sup> On April 5, 2016, the Exchange filed Amendment No. 3 to the proposed rule change.<sup>8</sup> The Commission received no comments on the proposed rule change. This order grants approval of the proposed rule change, as modified by Amendment Nos. 1, 2, and 3 thereto.

#### II. Exchange's Description of the Proposal

The Exchange proposes to list and trade the shares ("Shares") of the Europe Fund, Asia Pacific Fund, Emerging Markets Fund, and Developed International Fund (individually, "Fund," and collectively, "Funds") under Nasdaq Rule 5735, which governs the listing and trading of Managed Fund Shares on the Exchange. Each Fund, which will be a series of First Trust Exchange-Traded Fund III ("Trust"), will be an actively managed exchange-traded fund ("ETF"). The Shares will be offered by the Trust,<sup>9</sup> which was established as a Massachusetts business trust on January 9, 2008. The Trust is registered with the Commission as an investment company and has filed a registration statement on Form N-1A with the Commission.<sup>10</sup>

First Trust Advisors L.P. will be the investment adviser ("Adviser") to the

<sup>6</sup> 15 U.S.C. 78s(b)(2).

<sup>7</sup> See Securities Exchange Act Release No. 77192, 81 FR 9575 (February 25, 2016).

<sup>8</sup> In Amendment No. 3 to the proposed rule change, the Exchange clarified that: (a) All statements and representations made in the proposal regarding the description of the portfolios, limitations on portfolio holdings or reference assets, or the applicability of Exchange rules and surveillance procedures shall constitute continued listing requirements for listing the Shares on the Exchange; (b) the issuer will advise the Exchange of any failure by the Funds to comply with the continued listing requirements; (c) pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements; and (d) if a Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under the Nasdaq 5800 Series. Because Amendment No. 3 to the proposed rule change does not materially alter the substance of the proposed rule change or raise unique or novel regulatory issues, Amendment No. 3 is not subject to notice and comment (Amendment No. 3 is available at: <http://www.sec.gov/comments/sr-nasdaq-2015-161/nasdaq2015161-3.pdf>).

<sup>9</sup> According to the Exchange, the Trust has obtained certain exemptive relief under the Investment Company Act of 1940 ("1940 Act"). See Investment Company Act Release No. 28468 (October 27, 2008) (File No. 812-13477).

<sup>10</sup> See Post-Effective Amendment No. 29 to Registration Statement on Form N-1A for the Trust, dated November 19, 2015 (File Nos. 333-176976 and 811-22245) ("Registration Statement").

<sup>21</sup> 17 CFR 200.30-3(a)(12).

Funds. RiverFront Investment Group, LLC will serve as investment sub-adviser (“Sub-Adviser”) to the Funds and provide day-to-day portfolio management. First Trust Portfolios L.P. (“Distributor”) will be the principal underwriter and distributor of each Fund’s Shares. Brown Brothers Harriman & Co. will act as the administrator, accounting agent, custodian, and transfer agent to the Funds. According to the Exchange, neither the Adviser nor the Sub-Adviser is a broker-dealer, although the Adviser is affiliated with the Distributor, a broker-dealer, and the Sub-Adviser is affiliated with Robert W. Baird & Co. Incorporated, a broker-dealer. Each of the Adviser and Sub-Adviser has implemented a fire wall with respect to its respective broker-dealer affiliate regarding access to information concerning the composition or changes to a portfolio.<sup>11</sup>

The Exchange has made the following representations and statements describing the Funds and the Funds’ investment strategies, including the Funds’ portfolio holdings and investment restrictions.<sup>12</sup>

#### A. Exchange’s Description of Principal Investment Strategies Applicable to Each Fund

Each Fund’s investment objective will be to provide capital appreciation. Under normal market conditions,<sup>13</sup> each

<sup>11</sup> In the event (a) the Adviser or the Sub-Adviser registers as a broker-dealer, or becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with another broker-dealer, it will implement a fire wall with respect to its relevant personnel and/or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition of, and/or changes to, a portfolio and will be subject to procedures designed to prevent the use and dissemination of material, non-public information regarding such portfolio.

<sup>12</sup> Additional information regarding the Funds, the Trust, and the Shares, including investment strategies, risks, creation and redemption procedures, fees, portfolio holdings disclosure policies, calculation of net asset value (“NAV”), distributions, and taxes, among other things, can be found in the Notice, the amendments, and the Registration Statement, as applicable. See Notice, Amendment Nos. 1–3, and Registration Statement, *supra* notes 3, 4, 5, 8, and 10, respectively.

<sup>13</sup> The term “under normal market conditions” as used herein includes, but is not limited to, the absence of adverse market, economic, political or other conditions, including extreme volatility or trading halts in the securities markets or the financial markets generally; operational issues causing dissemination of inaccurate market information; or *force majeure* type events such as systems failure, natural or man-made disaster, act of God, armed conflict, act of terrorism, riot or labor disruption, or any similar intervening circumstance. On a temporary basis, including for defensive purposes, during the initial invest-up period and during periods of high cash inflows or outflows, a Fund may depart from its principal investment

Fund will seek to achieve its investment objective by investing at least 80% of its net assets (including investment borrowings) in a combination of: (i) “Principal Fund Equity Securities” (as defined below); (ii) forward currency contracts and non-deliverable forward currency contracts (collectively, “Forward Contracts”); and (iii) currency transactions on a spot (*i.e.*, cash) basis.<sup>14</sup>

For each Fund, (a) “Principal Equity Securities” will consist of the following U.S. and non-U.S. exchange-listed securities: (i) Common stocks; (ii) common and preferred shares of real estate investment trusts (“REITs”); and (iii) American Depositary Receipts (“ADRs”), European Depositary Receipts (“EDRs”), and Global Depositary Receipts (“GDRs”) and, together with ADRs and EDRs, collectively, “Depositary Receipts”;<sup>15</sup> and (b) “Principal Fund Equity Securities” will consist of Principal Equity Securities that are suggested by such Fund’s name.<sup>16</sup> Accordingly:

(1) For the Europe Fund, Principal Fund Equity Securities will be Principal Equity Securities of European companies;<sup>17</sup>

(2) for the Asia Pacific Fund, Principal Fund Equity Securities will be Principal Equity Securities of Asian Pacific companies;<sup>18</sup>

(3) for the Emerging Markets Fund, Principal Fund Equity Securities will be

strategies; for example, it may hold a higher than normal proportion of its assets in cash. During such periods, a Fund may not be able to achieve its investment objective. A Fund may adopt a defensive strategy when the Adviser and/or the Sub-Adviser believes securities in which such Fund normally invests have elevated risks due to political or economic factors and in other extraordinary circumstances.

<sup>14</sup> A Fund would enter into Forward Contracts and/or currency spot transactions for hedging purposes.

<sup>15</sup> The Funds will not invest in any unsponsored Depositary Receipts.

<sup>16</sup> With respect to Depositary Receipts, whether such Principal Equity Securities are Principal Fund Equity Securities is based on the underlying securities, the ownership of which is represented by the Depositary Receipts (*i.e.*, whether, as described below, the relevant underlying security is a security of a European company, an Asian Pacific company, an emerging market company, or a developed market company, as applicable).

<sup>17</sup> European companies are those companies (i) whose securities are traded principally on a stock exchange in a European country, (ii) that are organized under the laws of or have a principal office in a European country, or (iii) that have at least 50% of their assets in, or derive at least 50% of their revenues or profits from, a European country.

<sup>18</sup> Asian Pacific companies are those companies (i) whose securities are traded principally on a stock exchange in an Asian Pacific country, (ii) that are organized under the laws of or have a principal office in an Asian Pacific country, or (iii) that have at least 50% of their assets in, or derive at least 50% of their revenues or profits from, an Asian Pacific country.

Principal Equity Securities of emerging market companies;<sup>19</sup> and

(4) for the Developed International Fund, Principal Fund Equity Securities will be Principal Equity Securities of developed market companies.<sup>20</sup>

In selecting securities for a Fund, the Sub-Adviser will score individual securities from a portfolio of eligible securities according to several core attributes, using multiple proprietary factors within each core attribute. The Sub-Adviser will then rank each qualifying security based on its core attribute score, and the highest scoring securities will be considered for inclusion in the Fund’s portfolio. The Sub-Adviser will utilize its proprietary optimization process to maximize the percentage of high-scoring securities included in each Fund’s portfolio.

In addition, for each Fund, by entering into Forward Contracts and currency spot transactions, the Sub-Adviser will deploy a dynamic currency hedge (hedging up to 100% of such Fund’s foreign currency exposure) based on its proprietary hedging methodology. The Sub-Adviser’s hedging methodology will be constructed from a combination of quantitative measures and qualitative measures. Each Fund will only enter into transactions in Forward Contracts with counterparties that the Adviser and/or the Sub-Adviser reasonably believe are capable of performing under the applicable Forward Contract.<sup>21</sup>

#### B. Exchange’s Description of Other Investments for the Funds

According to the Exchange, each Fund may invest (in the aggregate) up to 20% of its net assets in the following securities and instruments.

<sup>19</sup> An emerging market company is one (i) domiciled or with a principal place of business or primary securities trading market in an emerging market country, or (ii) that derives a substantial portion of its total revenues or profits from emerging market countries.

<sup>20</sup> Developed market companies are those companies (i) whose securities are traded principally on a stock exchange in a developed market country, (ii) that are organized under the laws of or have a principal office in a developed market country, or (iii) that have at least 50% of their assets in, or derive at least 50% of their revenues or profits from, a developed market country.

<sup>21</sup> According to the Exchange, each Fund will seek, where possible, to use counterparties, as applicable, whose financial status is such that the risk of default is reduced; however, the risk of losses resulting from default is still possible. The Adviser and/or the Sub-Adviser will evaluate the creditworthiness of counterparties on an ongoing basis. In addition to information provided by credit agencies, the Adviser’s and/or Sub-Adviser’s analysis will evaluate each approved counterparty using various methods of analysis and may consider the Adviser’s and/or Sub-Adviser’s past experience with the counterparty, its known disciplinary history, and its share of market participation.

Each Fund may invest in the following U.S. and non-U.S. exchange-listed securities (other than Principal Fund Equity Securities): (i) Common stocks; (ii) common and preferred shares of REITs; (iii) Depositary Receipts; and (iv) equity securities of business development companies (collectively, "Other Equity Securities").<sup>22</sup>

Each Fund may invest in short-term debt securities and other short-term debt instruments (described below), as well as cash equivalents, or it may hold cash. The percentage of each Fund invested in such holdings or held in cash will vary and will depend on several factors, including market conditions. Each Fund may invest in the following short-term debt instruments:<sup>23</sup> (1) Fixed rate and floating rate U.S. government securities, including bills, notes, and bonds differing as to maturity and rates of interest, which are either issued or guaranteed by the U.S. Treasury or by U.S. government agencies or instrumentalities; (2) certificates of deposit issued against funds deposited in a bank or savings and loan association; (3) bankers' acceptances, which are short-term credit instruments used to finance commercial transactions; (4) repurchase agreements,<sup>24</sup> which involve purchases of debt securities; (5) bank time deposits, which are monies kept on deposit with banks or savings and loan associations for a stated period of time at a fixed rate of interest; (6) commercial paper, which is short-term unsecured promissory notes;<sup>25</sup> and (7) short-term debt obligations issued or guaranteed by non-U.S. governments or by their agencies or instrumentalities.

Each Fund may invest (but only up to 5% of its net assets) in exchange-listed equity index futures contracts.

<sup>22</sup> For each Fund, Other Equity Securities and Principal Fund Equity Securities are referred to collectively as "Equity Securities."

<sup>23</sup> The Exchange represents that short-term debt instruments will be issued by issuers having a long-term debt rating of at least A by Standard & Poor's Ratings Services ("S&P Ratings"), Moody's Investors Service, Inc. ("Moody's"), or Fitch Ratings ("Fitch"), and have a maturity of one year or less.

<sup>24</sup> According to the Exchange, each Fund intends to enter into repurchase agreements only with financial institutions and dealers believed by the Adviser and/or the Sub-Adviser to present minimal credit risks in accordance with criteria approved by the Board of Trustees of the Trust. The Adviser and/or the Sub-Adviser will review and monitor the creditworthiness of such institutions. The Adviser and/or the Sub-Adviser will monitor the value of the collateral at the time the transaction is entered into and at all times during the term of the repurchase agreement. The Funds will not enter into reverse repurchase agreements.

<sup>25</sup> Each Fund may only invest in commercial paper rated A-1 or higher by S&P Ratings, Prime-1 or higher by Moody's, or F1 or higher by Fitch.

### *C. Exchange's Description of the Funds' Equity Securities*

According to the Exchange, under normal market conditions, each Fund will invest in at least 20 Equity Securities. Each Fund will satisfy the "ISG Criteria" (as described below) and/or the "Alternative Criteria" (as described below).

A Fund will satisfy the ISG Criteria if at least 90% of such Fund's net assets that are invested (in the aggregate) in Equity Securities will be invested in Equity Securities that trade in markets that are members of the Intermarket Surveillance Group ("ISG")<sup>26</sup> or are parties to a comprehensive surveillance sharing agreement with the Exchange.

A Fund will satisfy the Alternative Criteria if, under normal market conditions, its Equity Securities meet the following criteria at the time of purchase and on a continuous basis: (1) Non-U.S. Equity Securities<sup>27</sup> each shall have a minimum market value of at least \$100 million; (2) non-U.S. Equity Securities each shall have a minimum global monthly trading volume of 250,000 shares, or minimum global notional volume traded per month of \$25,000,000, averaged over the last six months; (3) the most heavily weighted non-U.S. Equity Security shall not exceed 25% of the weight of the Fund's entire portfolio and, to the extent applicable, the five most heavily weighted non-U.S. Equity Securities shall not exceed 60% of the weight of the Fund's entire portfolio; (4) each non-U.S. Equity Security shall be listed and traded on an exchange that has last-sale reporting; and (5) all of such Fund's net assets that are invested (in the aggregate) in Equity Securities other than non-U.S. Equity Securities shall be invested in Equity Securities that trade in markets that are members of ISG or are parties to a comprehensive surveillance sharing agreement with the Exchange.

### *D. Exchange's Description of the Funds' Transactions in Forward Contracts and Exchange-Listed Equity Index Futures Contracts*

According to the Exchange, each Fund's transactions in Forward Contracts and exchange-listed equity index futures contracts will be consistent with its investment objective and the 1940 Act and will not be used

<sup>26</sup> For a list of the current members of ISG, see [www.isgportal.org](http://www.isgportal.org). The Exchange notes that not all components of the Disclosed Portfolio for a Fund may trade on markets that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

<sup>27</sup> For purposes of this filing, the term "non-U.S. Equity Securities" means Equity Securities that are not listed on a U.S. exchange.

to seek to achieve a multiple or inverse multiple of an index. Each Fund will comply with the regulatory requirements of the Commission with respect to coverage in connection with its transactions in Forward Contracts and exchange-listed equity index futures contracts. If the applicable guidelines prescribed under the 1940 Act so require, a Fund will earmark cash, U.S. government securities and/or other liquid assets permitted by the Commission in the amount prescribed.

### *E. Exchange's Description of the Funds' Investment Restrictions*

Each Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets (calculated at the time of investment), deemed illiquid by the Adviser and/or the Sub-Adviser.<sup>28</sup> Each 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 such Fund's net assets are held in illiquid assets. Illiquid assets include securities subject to contractual or other restrictions on resale and other instruments that lack readily available markets as determined in accordance with Commission staff guidance.

The Funds may not invest 25% or more of the value of their respective total assets in securities of issuers in any one industry. This restriction does not apply to (a) obligations issued or guaranteed by the U.S. government, its agencies or instrumentalities, or (b) securities of other investment companies.

Each Fund intends to qualify each year as a regulated investment company under Subchapter M of the Internal Revenue Code.

### **III. Discussion and Commission Findings**

After careful review, the Commission finds that the Exchange's proposal is consistent with the Exchange Act and the rules and regulations thereunder

<sup>28</sup> According to the Exchange, in determining the liquidity of the Funds' investments, the Adviser and/or the Sub-Adviser may consider the following factors: (i) The frequency of trades and quotes for the security or other instrument; (ii) the number of dealers wishing to purchase or sell the security or other instrument and the number of other potential purchasers; (iii) dealer undertakings to make a market in the security or other instrument; and (iv) the nature of the security or other instrument and the nature of the marketplace in which it trades (e.g., the time needed to dispose of the security or other instrument, the method of soliciting offers and the mechanics of transfer).

applicable to a national securities exchange.<sup>29</sup> In particular, the Commission finds that the proposed rule change, as modified by Amendment Nos. 1, 2, and 3 thereto, is consistent with Section 6(b)(5) of the Exchange Act,<sup>30</sup> which requires, among other things, that the Exchange's rules be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission also finds that the proposal is consistent with Section 11A(a)(1)(C)(iii) of the Exchange Act,<sup>31</sup> which sets forth Congress's finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers, and investors of information with respect to quotations for, and transactions in, securities.

Quotation and last-sale information for the Shares will be available via Nasdaq proprietary quote and trade services, as well as in accordance with the Unlisted Trading Privileges and the Consolidated Tape Association ("CTA") plans for the Shares. On each business day, before commencement of trading in Shares in the Regular Market Session<sup>32</sup> on the Exchange, each Fund will disclose on its Web site the Disclosed Portfolio held by such Fund that will form the basis for such Fund's calculation of NAV at the end of the business day.<sup>33</sup> The NAV of each Fund's

Shares generally will be calculated once daily Monday through Friday as of the close of regular trading on the New York Stock Exchange, generally 4:00 p.m., Eastern Time.<sup>34</sup>

In addition, the Intraday Indicative Value<sup>35</sup> for each Fund, available on the NASDAQ OMX Information LLC proprietary index data service, will be based upon the current value for the components of the Disclosed Portfolio and will be updated and widely disseminated by one or more major

holding in the Fund's portfolio. The Web site information will be publicly available at no charge.

<sup>34</sup> According to the Exchange, the Funds' investments will be valued daily. The following investments will typically be valued using information provided by a third-party pricing service ("Pricing Service"): (a) Except as provided below, short term U.S. government securities, commercial paper, bankers' acceptances, and short-term debt obligations issued or guaranteed by non-U.S. governments or by their agencies or instrumentalities (collectively, "Short Term Debt Instruments"); and (b) currency spot transactions. Debt instruments may be valued at evaluated mean prices, as provided by Pricing Services. Short Term Debt Instruments having a remaining maturity of 60 days or less when purchased will typically be valued at cost adjusted for amortization of premiums and accretion of discounts, provided the pricing committee of the Adviser ("Pricing Committee") has determined that the use of amortized cost is an appropriate reflection of value given market and issuer specific conditions existing at the time of the determination. Overnight repurchase agreements will be valued at amortized cost when it represents the best estimate of value. Term repurchase agreements (*i.e.*, those whose maturity exceeds seven days) will be valued at the average of the bid quotations obtained daily from at least two recognized dealers. Certificates of deposit and bank time deposits will typically be valued at cost. Equity Securities that are listed on any exchange other than the Exchange and the London Stock Exchange Alternative Investment Market ("AIM") will typically be valued at the last-sale price on the exchange on which they are principally traded on the business day as of which such value is being determined. Equity Securities listed on the Exchange or the AIM will typically be valued at the official closing price on the business day as of which such value is being determined. If there has been no sale on such day, or no official closing price in the case of securities traded on the Exchange or the AIM, such securities will typically be valued using fair value pricing. Equity Securities traded on more than one securities exchange will be valued at the last sale price or official closing price, as applicable, on the business day as of which such value is being determined at the close of the exchange representing the principal market for such securities. Exchange-listed equity index futures contracts will typically be valued at the closing price in the market where such instruments are principally traded. Forward 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. Assets 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. The value of assets denominated in foreign currencies will be converted into U.S. dollars at the exchange rates in effect at the time of valuation.

<sup>35</sup> Nasdaq Rule 5735(c)(3) defines the term "Intraday Indicative Value."

market data vendors and broadly displayed at least every 15 seconds during the Regular Market Session. The Intraday Indicative Value will be based on quotes and closing prices from the securities' local market and may not reflect events that occur subsequent to the local market's close.

Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. Quotation and last-sale information for the Equity Securities (to the extent traded on a U.S. exchange) will be available from the exchanges on which they are traded as well as in accordance with any applicable CTA plans. Pricing information for Short-Term Debt Instruments, repurchase agreements, Forward Contracts, bank time deposits, certificates of deposit, and currency spot transactions will be available from major broker-dealer firms and/or major market data vendors and/or Pricing Services. Pricing information for exchange-listed equity index futures contracts and non-U.S. Equity Securities will be available from the applicable listing exchange and from major market data vendors. In addition, the Exchange notes that the Funds' Web site will include a form of the prospectus for the Funds and additional data relating to NAV and other applicable quantitative information.

The Commission also believes that the proposal to list and trade the Shares is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading when a reasonable degree of transparency cannot be assured. The Exchange states that it will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time. The Exchange also represents that it may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of a Fund. The Exchange will halt trading in the Shares under the conditions specified in Nasdaq Rules 4120 and 4121, including the trading pauses under Nasdaq Rules 4120(a)(11) and (12). Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make

<sup>29</sup> In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

<sup>30</sup> 15 U.S.C. 78f(b)(5).

<sup>31</sup> 15 U.S.C. 78k-1(a)(1)(C)(iii).

<sup>32</sup> See Nasdaq Rule 4120(b)(4) (describing the three trading sessions on the Exchange: (1) Pre-Market Session from 4:00 a.m. to 9:30 a.m., Eastern Time; (2) Regular Market Session from 9:30 a.m. to 4:00 p.m. or 4:15 p.m., Eastern Time; and (3) Post-Market Session from 4:00 p.m. or 4:15 p.m. to 8:00 p.m., Eastern Time).

<sup>33</sup> Nasdaq Rule 5735(c)(2) defines the term "Disclosed Portfolio." According to the Exchange, each Fund's disclosure of derivative positions in the Disclosed Portfolio will include sufficient information for market participants to use to value these positions intraday. On a daily basis, each Fund will also disclose on its 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); the identity of the security, index, or other asset or instrument underlying the holding, if any; 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 percentage weighting of the

trading in the Shares inadvisable.<sup>36</sup> Trading in the Shares also will be subject to Rule 5735(d)(2)(D), which sets forth circumstances under which Shares of a Fund may be halted.

The Exchange states that it has a general policy prohibiting the distribution of material, non-public information by its employees. The Exchange further states that neither the Adviser nor the Sub-Adviser is a broker-dealer, but each is affiliated with a broker-dealer, and that the Adviser and Sub-Adviser has each implemented a fire wall with respect to its respective broker-dealer affiliate regarding access to information concerning the composition of, and changes to, each Fund's portfolio.<sup>37</sup> Further, the Commission notes that the Reporting Authority<sup>38</sup> that provides the Disclosed Portfolio must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material, non-public information regarding the actual components of the portfolio.<sup>39</sup> The Exchange represents that trading in the Shares will be subject to the existing trading surveillances, administered by both Nasdaq and also 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.<sup>40</sup>

Nasdaq deems the Shares to be equity securities, thus rendering trading in the Shares subject to Nasdaq's existing rules governing the trading of equity securities. In support of this proposal, the Exchange represented that:

(1) The Shares will be subject to Nasdaq Rule 5735, which sets forth the initial and continued listing criteria applicable to Managed Fund Shares.

(2) Trading in the Shares will be subject to the existing trading surveillances, administered by both Nasdaq and FINRA on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws. 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 applicable federal securities laws.

(3) FINRA, on behalf of the Exchange, will communicate as needed regarding trading in the Shares and certain of the Equity Securities and exchange-listed equity index futures contracts held by the Funds with other markets and other entities that are members of ISG, and FINRA may obtain trading information regarding trading in the Shares and such securities and instruments held by the Funds from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and certain of the Equity Securities and exchange-listed equity index futures contracts held by the Funds from markets and other entities that are members of ISG, which includes securities and futures exchanges, or with which the Exchange has in place a comprehensive surveillance sharing agreement. Moreover, FINRA, on behalf of the Exchange, will be able to access, as needed, trade information for certain fixed income securities held by the Funds reported to FINRA's Trade Reporting and Compliance Engine ("TRACE").

(4) For each Fund, at least 90% of such Fund's net assets that are invested (in the aggregate) in exchange-listed equity index futures contracts will be invested in instruments that trade in markets that are members of ISG or are parties to a comprehensive surveillance sharing agreement with the Exchange.

(5) The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions.

(6) Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular for each Fund will discuss the following: (a) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (b) Nasdaq Rule 2111A, which imposes suitability obligations on Nasdaq members with respect to recommending transactions in the Shares to customers; (c) how information regarding the Intraday Indicative Value and the Disclosed Portfolio is disseminated; (d) the risks involved in trading the Shares during the Pre-Market and Post-Market Sessions when an updated Intraday Indicative Value will not be calculated or publicly disseminated; (e) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (f) trading information.

(7) For initial and continued listing, the Funds must be in compliance with Rule 10A-3 under the Act.<sup>41</sup>

(8) Each Fund may hold up to an aggregate amount of 15% of its net assets in illiquid assets.

(9) The Pricing Committee will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding each Fund's portfolio.

(10) Each Fund will satisfy: (a) The ISG Criteria; and/or (b) the Alternative Criteria at the time of purchase and on a continuous basis.

(11) A minimum of 100,000 Shares will be outstanding at the commencement of trading on the Exchange.

The Exchange represents that all statements and representations made in the filing regarding (a) the description of the portfolios, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange rules and surveillance procedures shall constitute continued listing requirements for listing the Shares on the Exchange. In addition, the issuer has represented to the Exchange that it will advise the Exchange of any failure by the Funds to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements.<sup>42</sup> If a Fund is not in

<sup>36</sup> These may include: (1) The extent to which trading is not occurring in the securities and/or the other assets constituting the Disclosed Portfolio of a Fund; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present.

<sup>37</sup> See *supra* note 11 and accompanying text. The Exchange further represents that an investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 ("Advisers Act"). As a result, the Adviser, the Sub-Adviser, and their related personnel are subject to the provisions of Rule 204A-1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A-1 under the Advisers Act. In addition, Rule 206(4)-7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violation, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above.

<sup>38</sup> Nasdaq Rule 5735(c)(4) defines "Reporting Authority."

<sup>39</sup> See Nasdaq Rule 5735(d)(2)(B)(ii).

<sup>40</sup> The Exchange represents that FINRA surveils trading on the Exchange pursuant to a regulatory services agreement and that the Exchange is responsible for FINRA's performance under this regulatory services agreement.

<sup>41</sup> See 17 CFR 240.10A-3.

<sup>42</sup> The Commission notes that certain other proposals for the listing and trading of Managed

compliance with the applicable listing requirements, the Exchange will commence delisting procedures under the Nasdaq 5800 Series. This approval order is based on all of the Exchange's representations, including those set forth above, in the Notice, and in Amendment Nos. 1, 2, and 3 to the proposed rule change. The Commission notes that the Funds and the Shares must comply with the requirements of Nasdaq Rule 5735, including those set forth in this proposed rule change, as modified by Amendment Nos. 1, 2, and 3 thereto, to be listed and traded on the Exchange on an initial and continuing basis.

For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment Nos. 1, 2, and 3 thereto, is consistent with Section 6(b)(5) of the Act<sup>43</sup> and the rules and regulations thereunder applicable to a national securities exchange.

**IV. Conclusion**

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act,<sup>44</sup> that the proposed rule change (SR-NASDAQ-2015-161), as modified by Amendment Nos. 1, 2, and 3 thereto, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority,<sup>45</sup>

**Robert W. Errett,**

*Deputy Secretary.*

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**BILLING CODE 8011-01-P**

Fund Shares include a representation that the exchange will "surveil" for compliance with the continued listing requirements. *See, e.g.,* Amendment No. 2 to SR-BATS-2016-04, available at: <http://www.sec.gov/comments/sr-bats-2016-04/bats201604-2.pdf>. In the context of this representation, it is the Commission's view that "monitor" and "surveil" both mean ongoing oversight of the Fund's compliance with the continued listing requirements. Therefore, the Commission does not view "monitor" as a more or less stringent obligation than "surveil" with respect to the continued listing requirements.

<sup>43</sup> 15 U.S.C. 78f(b)(5).

<sup>44</sup> 15 U.S.C. 78s(b)(2).

<sup>45</sup> 17 CFR 200.30-3(a)(12).

**SECURITIES AND EXCHANGE COMMISSION**

[Release No. 34-77545; File No. SR-Phlx-2016-44]

**Self-Regulatory Organizations; NASDAQ PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 1064**

April 6, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> and Rule 19b-4 thereunder,<sup>2</sup> notice is hereby given that on April 1, 2016, NASDAQ PHLX LLC ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

**I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change**

The Exchange proposes to delete two incorrect cross-references in Rule 1064, Crossing, Facilitation and Solicited Orders.

The text of the proposed rule change is detailed below: Proposed new language is in italics and proposed deletions are in brackets.

\* \* \* \* \*

NASDAQ PHLX Rules

\* \* \* \* \*

Options Rules

Rules Applicable To Trading of Options on Stocks, Exchange-Traded Fund Shares and Foreign Currencies (Rules 1000-1095)

\* \* \* \* \*

Rule 1064. Crossing, Facilitation and Solicited Orders

(a)-(c) No change.

(d) No change.

(i)-(ii) No change.

(iii) No change.

(A)-(F) No change.

(G) prior to entering tied hedge orders on behalf of customers, the member or member organization must deliver to the customer a written notification informing the customer that his order may be executed using the Exchange's tied hedge procedures. The written notification must disclose the terms and conditions contained [in this

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

Commentary] herein and be in a form approved by the Exchange. A combination option and hedging position offered in reliance on this [Commentary .04] provision shall be referred to as a "tied hedge" order.

(H)-(I) No change.

(e) No change.

• • • Commentary: -----

.01-.02 No change.

\* \* \* \* \*

**II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

*A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change*

1. Purpose

The purpose of the filing is to correct Rule 1064 by deleting two references to the "commentary" to the rule, which no longer exists. The Exchange recently deleted Commentary .04<sup>3</sup> by incorporating its provisions into paragraph (d)(iii), because it was related to the anticipatory hedging provisions in paragraph (d). The Exchange inadvertently omitted the deletion of these two references to Commentary .04 in new Rule 1064(d)(iii)(G). Accordingly, this provision refers to a commentary that does not exist.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act<sup>4</sup> in general, and furthers the objectives of Section 6(b)(5) of the Act<sup>5</sup> in particular, in that it is designed to promote just and equitable principles of trade and to protect investors and the public interest by correcting a provision, which should help prevent confusion and ensure the accuracy of the rulebook.

<sup>3</sup> Securities Exchange Act Release No. 76984 (January 28, 2016), 81 FR 5796 (February 3, 2016) (SR-Phlx-2016-07).

<sup>4</sup> 15 U.S.C. 78f(b).

<sup>5</sup> 15 U.S.C. 78f(b)(5).

### B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. This minor correction does not impact competition.

### C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

### III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act<sup>6</sup> and subparagraph (f)(6) of Rule 19b-4 thereunder.<sup>7</sup>

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: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

### IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

#### Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-Phlx-2016-44 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-Phlx-2016-44. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (<http://www.sec.gov/rules/sro.shtml>). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-Phlx-2016-44 and should be submitted on or before May 3, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>8</sup>

**Robert W. Errett,**

*Deputy Secretary.*

[FR Doc. 2016-08305 Filed 4-11-16; 8:45 am]

**BILLING CODE 8011-01-P**

### SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-77538; File No. SR-EDGX-2016-06]

### Self-Regulatory Organizations; EDGX Exchange, Inc.; Order Approving Proposed Rule Change, as Modified by Amendment No. 1 Thereto, To Adopt an Early Trading Session and Three New Time-In-Force Instructions

April 6, 2016.

#### I. Introduction

On February 2, 2016, EDGX Exchange, Inc. (the "Exchange" or "EDGX") filed with the Securities and Exchange Commission (the "Commission"), pursuant to Section 19(b)(1)<sup>1</sup> of the Securities Exchange Act of 1934 ("Act")<sup>2</sup> and Rule 19b-4 thereunder,<sup>3</sup> a proposed rule change to amend its rules to: (i) Create a new trading session to be known as the Early Trading Session, which will run from 7:00 a.m. to 8:00 a.m. Eastern Time; and (ii) adopt three new Time-in-Force ("TIF") instructions. On February 12, 2016, the Exchange filed Amendment No. 1 to the proposed rule change.<sup>4</sup> The proposed rule change, as modified by Amendment No. 1 thereto, was published for comment in the **Federal Register** on February 22, 2016.<sup>5</sup> The Commission received no comments on the proposed rule change. This order approves the proposed rule change, as modified by Amendment No. 1.

#### II. Description of the Proposal

The Exchange proposes to amend its rules to: (i) Create a new trading session, the Early Trading Session, which will run from 7:00 a.m. to 8:00 a.m. Eastern Time; and (ii) adopt three new TIF instructions.<sup>6</sup>

##### A. Early Trading Session

The Exchange trading day is currently divided into three sessions: (i) The Pre-Opening Session which starts at 8:00 a.m. and ends at 9:30 a.m. Eastern Time; (ii) Regular Trading Hours which runs from 9:30 a.m. to 4:00 p.m. Eastern Time; and (iii) the Post-Closing Session, which runs from 4:00 p.m. to 8:00 p.m.

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 15 U.S.C. 78a.

<sup>3</sup> 17 CFR 240.19b-4.

<sup>4</sup> In Amendment No. 1, the Exchange noted that it would subject orders that are eligible for execution at the start of the Pre-Opening Session to all of the Exchange's standard regulatory checks, including compliance with Regulation NMS, Regulation SHO as well as other relevant Exchange rules.

<sup>5</sup> See Securities Exchange Act Release No. 77142 (February 16, 2016), 81 FR 8806 ("Notice").

<sup>6</sup> See Notice, *supra* note 5.

<sup>6</sup> 15 U.S.C. 78s(b)(3)(a)(iii).

<sup>7</sup> 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.

<sup>8</sup> 17 CFR 200.30-3(a)(12).

Eastern Time. The Exchange proposes to amend its rules to create the Early Trading Session. Exchange Rule 1.5 would be amended to add a new term, "Early Trading Session," under proposed paragraph (ii). "Early Trading Session" would be defined as "the time between 7:00 a.m. and 8:00 a.m. Eastern Time."

The Exchange also proposes to amend Exchange Rule 11.1(a) to state that orders may be entered or executed on, or routed away from, the Exchange during the the Early Trading Session and to reflect the start time of the Early Trading Session as 7:00 a.m. Eastern Time. Other than the proposal to adopt an Early Trading Session, the Exchange does not propose to amend the substance or operation of Exchange Rule 11.1(a).<sup>7</sup>

Users<sup>8</sup> currently designate when their orders are eligible for execution by selecting a desired TIF instruction.<sup>9</sup> Orders entered between 6:00 a.m. and 8:00 a.m. Eastern Time are not eligible for execution until the start of the Pre-Opening Session or Regular Trading Hours, depending on the TIF selected by the User. Users may enter orders in advance of the trading session for which the order is eligible. For example, Users may enter orders starting at 6:00 a.m. Eastern Time with a TIF of Regular Hours Only ("RHO"), which designates that the order only be eligible for execution during Regular Trading Hours.<sup>10</sup> Users may enter orders as early as 6:00 a.m. Eastern Time, but those orders would not be eligible for execution until the start of the Pre-Opening Session at 8:00 a.m. According to the Exchange, some Users have requested the ability for their orders to be eligible for execution starting at 7:00 a.m. Eastern Time. Therefore, the Exchange is proposing to adopt the Early Trading Session.<sup>11</sup>

As amended, Exchange Rule 11.1(a)(1) would state that orders entered between 6:00 a.m. and 7:00 a.m. Eastern Time, rather than 6:00 a.m. and 8:00 a.m. Eastern Time, would not be eligible for execution until the start of the Early Trading Session, Pre-Opening Session, or Regular Trading Hours, depending on the TIF selected by the User. Exchange Rule 11.1(a)(1) will also be amended to state that the Exchange will not accept the following orders prior to 7:00 a.m. Eastern Time, rather than 8:00 a.m.:

Orders with a Post Only instruction,<sup>12</sup> Intermarket Sweep Orders ("ISOs"),<sup>13</sup> Market Orders<sup>14</sup> with a TIF other than Regular Hours Only, orders with a Minimum Execution Quantity instruction<sup>15</sup> that also include a TIF of Regular Hours Only, and all orders with a TIF instruction of Immediate-or-Cancel ("IOC")<sup>16</sup> or Fill-or-Kill ("FOK").<sup>17</sup> At the commencement of the Early Trading Session, orders entered between 6:00 a.m. and 7:00 a.m. Eastern Time, rather than 6:00 a.m. and 8:00 a.m. Eastern Time, will be handled in time sequence, beginning with the order with the oldest time stamp, and will be placed on the EDGX Book,<sup>18</sup> routed, cancelled, or executed in accordance with the terms of the order. As amended, Exchange Rule 11.1(a) would state that orders may be executed on the Exchange or routed away from the Exchange during Regular Trading Hours and during the Early Trading, Pre-Opening, Regular and Post Closing Sessions.<sup>19</sup>

The Exchange also proposes to make the changes described below to Exchange Rules 3.21, 11.8, 11.10, 11.15, 14.1, 14.2 and 14.3 to reflect the adoption of the Early Trading Session:

- Exchange Rule 3.21, Customer Disclosures. Exchange Rule 3.21 prohibits Members from accepting an order from a customer for execution in the Pre-Opening or Post-Closing Session without disclosing to their customer that extended hours trading involves material trading risks, including the possibility of lower liquidity, high volatility, changing prices, unlinked markets, an exaggerated effect from news announcements, wider spreads and any other relevant risk. The Exchange proposes to amend Exchange Rule 3.21 to also require such disclosures for customer orders that are to be executed during the Early Trading Session.

- Exchange Rules 11.8(b), (c), (d), and (f). The Exchange proposes to amend the description of Limit Orders under Exchange Rule 11.8(b), ISOs under

Exchange Rule 11.8(c), MidPoint Peg Orders under Exchange Rule 11.8(d), and Supplemental Peg Orders under Exchange Rule 11.8(f) to account for the Early Trading Session. Every order type that is currently available beginning at 8:00 a.m. will be available beginning at 7:00 a.m. for inclusion in the Early Trading Session. All other order types, and all order type behaviors, will otherwise remain unchanged. Therefore, each of the above rules for Limit Orders, ISOs, MidPoint Peg Orders, and Supplemental Peg Orders would be amended to state that those order types are available during the Early Trading Session.

- Exchange Rules 11.8(a) and (e). Market Orders and Market Maker Peg Orders would not be eligible for execution during the Early Trading Session. Market Orders are only eligible for execution during the Regular Session.<sup>20</sup> Market Maker Peg Orders may currently be submitted to the Exchange starting at the beginning of the Pre-Opening Session, but the order will not be executable or automatically priced until after the first regular way transaction on the listing exchange in the security, as reported by the responsible single plan processor. Exchange Rule 11.8(e)(7) would be amended to state that Market Maker Peg Orders may be submitted to the Exchange starting at the beginning of the Early Trading Session. Market Maker Peg Orders would continue to not be executable or automatically priced until after the first regular way transaction on the listing exchange in the security, as reported by the responsible single plan processor.

- Exchange Rule 11.10, Order Execution and Routing. Exchange Rule 11.10(a)(2) discusses compliance with Regulation NMS and Trade Through Protections and states that the price of any execution occurring during the Pre-Opening Session or the Post-Closing Session must be equal to or better than the highest Protected Bid or lowest Protected Offer, unless the order is marked ISO or a Protected Bid is crossing a Protected Offer. The Exchange proposes to amend Exchange Rule 11.10(a)(2) to expand the rule's requirements to the Early Trading Session.

- Exchange Rule 11.15, Clearly Erroneous Executions. Exchange Rule 11.15 outlines under which conditions the Exchange may determine that an execution is clearly erroneous. The Exchange proposes to amend Exchange Rule 11.15 to include executions that occur during the Early Trading Session.

<sup>20</sup> See Exchange Rule 11.8(a)(5).

<sup>7</sup> See *id.* at 8806.

<sup>8</sup> "User" is defined as "any Member or Sponsored Participant who is authorized to obtain access to the System pursuant to Rule 11.3." See Exchange Rule 1.5(ee).

<sup>9</sup> See Exchange Rule 11.6(q).

<sup>10</sup> See Exchange Rule 11.6(q)(6).

<sup>11</sup> See Notice, *supra* note 5, at 8806.

<sup>12</sup> See Exchange Rule 11.6(n)(4).

<sup>13</sup> See Exchange Rule 11.8(c).

<sup>14</sup> See Exchange Rule 11.8(a).

<sup>15</sup> See Exchange Rule 11.6(h).

<sup>16</sup> See Exchange Rule 11.6(q)(1).

<sup>17</sup> See Exchange Rule 11.6(q)(3).

<sup>18</sup> See Exchange Rule 1.5(d).

<sup>19</sup> The Exchange also describes how the Early Trading Session will affect its Members' operations and the Exchange's opening process, order types, routing services, order processing, data feeds, trade reporting, market surveillance, and clearly erroneous trade processing. The Exchange clarifies that these processes will operate in the same manner with the exception of changes in time to reflect the adoption of the Early Trading Session. See Notice, *supra* note 5, at 8807.



Exchange Rule 11.15(c)(1) sets forth the numerical guidelines the Exchange is to follow when determining whether an execution was clearly erroneous during Regular Trading Hours or the Pre-Opening or Post-Closing Trading Session. Exchange Rule 11.15(c)(3) sets forth additional factors the Exchange may consider in determining whether a transaction is clearly erroneous. These factors include whether the transaction was executed during the Pre-Opening or Post-Closing Trading Sessions. The Exchange proposes to amend Exchange Rule 11.15(c)(1) and (3) to include executions occurring during the Early Trading Session.

- Exchange Rule 14.1, Unlisted Trading Privileges. The Exchange proposes to amend Exchange Rules 14.1(c)(2), and Interpretation and Policies .01(a) and (b) to account for the Early Trading Session. Specifically, the Exchange proposes to amend paragraph (c)(2) to state that an information circular distributed by the Exchange prior to the commencement of trading of a UTP Derivative Security<sup>21</sup> will describe the risk of trading during the Early Trading Session.<sup>22</sup> In addition, the Exchange proposes to amend Interpretation and Policies .01(a) to add Early Trading Session to the paragraph's title and to state that if a UTP Derivative Security begins trading on the Exchange in the Early Trading Session or Pre-Opening Session and subsequently a temporary interruption occurs in the calculation or wide dissemination of the Intraday Indicative Value ("IIV") or the value of the underlying index, as applicable, to such UTP Derivative Security, by a major market data vendor, the Exchange may continue to trade the UTP Derivative Security for the remainder of the Early Trading Session and Pre-Opening Session. Lastly, the Exchange proposes to amend Interpretation and Policies .01(b) to add Early Trading Session to the paragraph's title and to amend subparagraph (2) of that section to state that if the IIV or the value of the underlying index continues not to be calculated or widely available as of the commencement of the Early Trading Session or Pre-Opening Session on the next business day, the Exchange shall not commence trading of the UTP Derivative Security in the Early Trading Session or Pre-Opening Session that day.

- Exchange Rule 14.2, Investment Company Units. The Exchange proposes to amend Exchange Rule 14.2(g) to state

that transactions in Investment Company Units may occur during the Early Trading Session. Currently, such transactions may occur during Regular Trading Hours and the Pre-Opening and Post Closing Sessions.

- Exchange Rule 14.3, Trust Issued Receipts. The Exchange proposes to amend Exchange Rule 14.3(d) to state that transactions in Trust Issued Receipts may occur during the Early Trading Session. Currently, such transactions may occur during Regular Trading Hours and the Pre-Opening and Post-Closing Sessions.

#### B. TIF Instructions

The Exchange proposes to adopt three new TIF instructions under Exchange Rule 11.6(q).<sup>23</sup> As discussed above, a User may designate when its order is eligible for execution by selecting the desired TIF instruction under Exchange Rule 11.6(q).<sup>24</sup>

Although the Exchange states that the proposal to adopt an Early Trading Session is in response to User requests for their orders to be eligible for execution starting at 7:00 a.m. Eastern Time, some Users have requested that their orders continue to not be eligible for execution until the start of the Pre-Opening Session at 8:00 a.m.<sup>25</sup> Therefore, the Exchange proposes to adopt the following three new TIF instructions under Exchange Rule 11.6(q):

- Pre-Opening Session Plus ("PRE"). A limit order that is designated for execution during the Pre-Opening Session and Regular Trading Hours. Like the current Day TIF instruction,<sup>26</sup> any portion not executed expires at the end of Regular Trading Hours.

- Pre-Opening Session 'til Extended Day ("PTX"). A limit order that is designated for execution during the Pre-Opening Session, Regular Trading Hours, and the Post-Closing Session. Like the current GTX TIF instruction,<sup>27</sup> any portion not executed expires at the end of the Post-Closing Session.

- Pre-Opening Session 'til Day ("PTD"). A limit order that is designated for execution during the Pre-Opening Session, Regular Trading Hours, and the Post-Closing Session. Like the current

GTD TIF instruction,<sup>28</sup> any portion not executed will be cancelled at the expiration time assigned to the order, which can be no later than the close of the Post-Closing Trading Session.

Under each proposed TIF instruction, Users may designate that their orders only be eligible for execution starting with the Pre-Opening Session. Users may continue to enter orders as early as 6:00 a.m., but orders with the proposed TIF instructions would not be eligible for execution until 8:00 a.m. Eastern Time, the start of the Pre-Opening Session.<sup>29</sup> At the commencement of the Pre-Opening Session, orders entered between 6:00 a.m. and 8:00 a.m. Eastern Time with one of the proposed TIF instructions will be handled in time sequence, beginning with the order with the oldest time stamp, and will be placed on the EDGX Book, routed, cancelled, or executed in accordance with the terms of the order.<sup>30</sup>

The Exchange proposes to amend the following order types under Exchange Rule 11.8 to account for the three proposed TIF instructions:

- Market Orders. The proposed TIF instruction of PRE, PTX, and PTD would not be available for Market Orders. Under Exchange Rule 11.8(a)(2), a Market Order may only include a TIF instruction of IOC, RHO, FOK, or Day.

- Limit Orders. Exchange Rule 11.8(b)(2) describes the TIF instructions that may be attached to a Limit Order. The Exchange proposes to amend paragraph (b)(2) to add the TIF instructions of PRE, PTX, or PTD to the list of TIF instructions that a Limit Order may include.

- ISOs. Exchange Rule 11.8(c)(1) describes the TIF instructions that may be attached to an incoming ISO. The Exchange proposes to amend paragraph (c)(1) to state that an incoming ISO may have a TIF instruction of PRE, PTX, or PTD, in addition to Day, GTD, RHO, GTX, and IOC. Exchange Rule 11.8(c)(1) would be further amended to state that an incoming ISO with a Post Only and TIF instruction of PRE, PTX, or PTD, like those with a TIF instruction or GTD, GTX, or Day, will be cancelled without execution if, when entered, it is immediately marketable against an order with a Displayed instruction resting in the EDGX Book unless such order removes liquidity pursuant to Exchange Rule 11.6(n)(4).<sup>31</sup>

<sup>28</sup> See Exchange Rule 11.6(q)(4).

<sup>29</sup> Orders utilizing one of the proposed TIF instructions would not be eligible for execution during the Early Trading Session.

<sup>30</sup> See Exchange Rule 11.1(a).

<sup>31</sup> Exchange Rule 11.6(n)(4) defines the Post Only instruction and states, in sum, that an order with a Post Only instruction and a Display-Price Sliding

<sup>21</sup> See Exchange Rule 14.1(c).

<sup>22</sup> Currently, the information circular describes only those risks in the Pre-Opening and Post-Closing Trading Sessions.

<sup>23</sup> The Exchange also proposes to amend the descriptions of Good-'til Day ("GTD") under Exchange Rule 11.6(q)(4) and Good-'til Extended Day ("GTX") under Exchange Rule 11.6(q)(5) to replace incorrect references to the Post-Market Session with Post-Closing Session, as Post-Closing Session is the accurate term under Exchange Rule 1.5(r).

<sup>24</sup> See Exchange Rule 11.1(a)(1).

<sup>25</sup> See Notice, *supra* note 5, at 8808.

<sup>26</sup> See Exchange Rule 11.6(q)(2).

<sup>27</sup> See Exchange Rule 11.6(q)(5).

- MidPoint Peg Orders. Exchange Rule 11.8(d)(1) describes the TIF instructions that may be attached to a MidPoint Peg Order. The Exchange proposes to amend paragraph (d)(1) to state that a MidPoint Peg Order may have a TIF instruction of PRE, PTX, or PTD, in addition to Day, FOK, IOC, RHO, GTX and GTD.

- Market Maker Peg Orders. The proposed TIF instruction of PRE, PTX, and PTD would not be available to Market Maker Peg Orders. Under Exchange Rule 11.8(e)(4), a Market Maker Peg Order may only include a TIF instruction of Day, RHO, or GTD.

- Supplemental Peg. Exchange Rule 11.8(f)(1) describes the TIF instructions that may be attached to a Supplemental Peg Order. The Exchange proposes to amend paragraph (f)(1) to state that a Supplemental Peg Order may have a TIF instruction of PRE, PTX, or PTD, in addition to GTD, GTX, RHO and Day.

### III. Discussion and Commission Findings

After careful consideration, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.<sup>32</sup> The Commission believes that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5)<sup>33</sup> in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange proposes to adopt an Early Trading Session and three new TIF instructions and to make related changes to its rules as discussed above.<sup>34</sup> The Commission believes that the proposed rules would provide Users

or Price Adjust instruction will remove contra-side liquidity from the EDGX Book if the order is an order to buy or sell a security priced below \$1.00 or if the value of such execution when removing liquidity equals or exceeds the value of such execution if the order instead posted to the EDGX Book and subsequently provided liquidity, including the applicable fees charged or rebates provided.

<sup>32</sup> In approving this rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

<sup>33</sup> 15 U.S.C. 78f(b)(5).

<sup>34</sup> See *supra* section II.

with additional options for trading on the Exchange. The Commission notes that the proposed Early Trading Session hours are similar to those of other exchanges<sup>35</sup> and that the proposed TIF instructions would offer functionality similar to existing functionality available on the Exchange and other exchanges which allows Members to select when their orders become eligible for execution.<sup>36</sup>

The Commission notes that the Exchange has represented that it would subject orders that are eligible for execution as of the start of the Pre-Opening Session to all of the Exchange's standard regulatory checks, as it currently does with all orders upon entry.<sup>37</sup> Specifically, the Exchange will subject such orders to checks for compliance with, including but not limited to, Regulation NMS,<sup>38</sup> Regulation SHO,<sup>39</sup> and relevant Exchange rules. Moreover, the Exchange reminds its Members of their regulatory obligations when submitting an order with one of the proposed TIF instructions.<sup>40</sup> In particular, the Exchange states that Members must comply with the Market Access Rule,<sup>41</sup> which requires, among other things, pre-trade controls and procedures that are reasonably designed to assure compliance with Exchange trading rules and Commission rules pursuant to Regulation SHO and Regulation NMS. The Exchange also notes that a Member's procedures must be reasonably designed to ensure compliance with the applicable regulatory requirements, not just at the time the order is routed to the Exchange, but also at the time the order becomes eligible for execution.<sup>42</sup>

The Commission further notes the Exchange's discussion of the best execution obligations of Members utilizing the proposed TIF

<sup>35</sup> For example, NYSE Arca, Inc. operates an Opening Session that starts at 4:00 a.m. Eastern Time and ends at 9:30 a.m. Eastern Time and Nasdaq Stock Market LLC operates a pre-market session that also opens at 4:00 a.m. and ends at 9:30 a.m. Eastern Time. See NYSE Arca Rule 7.34(a)(1); Nasdaq Rule 4701(g); see also Securities Exchange Act Release No. 60605 (September 1, 2009), 74 FR 46277 (September 8, 2009) (SR-CHX-2009-13) (adopting bifurcated post-trading session on the Chicago Stock Exchange, Inc.).

<sup>36</sup> Specifically, on the Exchange, Users may enter an order starting at 6:00 a.m. Eastern Time with a TIF of Regular Hours Only, which designates that the order only be eligible for execution during Regular Trading Hours, which begin at 9:30 a.m. Eastern Time. See Exchange Rule 11.6(q)(6); see also NASDAQ Rule 4703(a)(7).

<sup>37</sup> See Amendment No. 1, *supra* note 4.

<sup>38</sup> See 17 CFR 242.600–613.

<sup>39</sup> See 17 CFR 242.200–204.

<sup>40</sup> See Notice, *supra* note 5, at 8811.

<sup>41</sup> See 17 CFR 240.15c3–5.

<sup>42</sup> See Notice, *supra* note 5, at 8811.

instructions.<sup>43</sup> Specifically, the Exchange states that a Member's best execution obligations may include cancelling an order when market conditions deteriorate and could result in an inferior execution or informing customers if the execution of their order may be delayed intentionally while the Member utilizes reasonable diligence to ascertain the best market for the security.<sup>44</sup> The Exchange further notes that Members will maintain the ability to cancel or modify the terms of an order utilizing any of the proposed TIF instructions at any time, including during the time from when the order is routed to the Exchange until the start of the Pre-Opening Session. As a result, the Exchange states that a Member who utilizes the proposed TIF instructions, but later determines that market conditions favor execution during the Early Trading Session, can cancel the order residing at the Exchange and enter a separate order to execute during the Early Trading Session.<sup>45</sup>

### IV. Conclusion

*It is therefore ordered*, pursuant to Section 19(b)(2) of the Act<sup>46</sup> that the proposed rule change (SR-EDGX-2016-06), as modified by Amendment No. 1, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>47</sup>

**Robert W. Errett,**

*Deputy Secretary.*

[FR Doc. 2016-08302 Filed 4-11-16; 8:45 am]

BILLING CODE 8011-01-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 Investor Advisory Committee will hold a meeting on Thursday, April 14, 2016, in Multi-Purpose Room LL-006 at the Commission's headquarters, 100 F Street NE., Washington, DC. The meeting will begin at 9:30 a.m. (ET) and will be open to the public. Seating will be on a first-come, first-served basis. Doors will open at 9:00 a.m. Visitors will be subject to security checks. The meeting will be webcast on the Commission's Web site at [www.sec.gov](http://www.sec.gov).

<sup>43</sup> See *id.* at 8810–11.

<sup>44</sup> *Id.* at 8810 n.45.

<sup>45</sup> *Id.* at 8810.

<sup>46</sup> 15 U.S.C. 78s(b)(2).

<sup>47</sup> 17 CFR 200.30-3(a)(12).

On March 23, 2016, the Commission issued notice of the Committee meeting (Release No. 33-10058), indicating that the meeting is open to the public (except during that portion of the meeting reserved for an administrative work session during lunch), and inviting the public to submit written comments to the Committee. This Sunshine Act notice is being issued because a quorum of the Commission may attend the meeting.

The agenda for the meeting includes: Remarks from Commissioners; a discussion of a recommendation of the Investor as Purchaser subcommittee regarding mutual fund cost disclosure; an update from the Commission's Office of Compliance Inspections and Examinations; subcommittee reports; a discussion regarding cybersecurity and related investor protection concerns; reflections on the first full term of Investor Advisory Committee membership; and a nonpublic administrative work session during lunch.

For further information, please contact the Office of the Secretary at (202) 551-5400.

Dated: April 7, 2016.

**Brent J. Fields,**  
Secretary.

[FR Doc. 2016-08445 Filed 4-8-16; 11:15 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-77536; File No. SR-NYSEMKT-2016-26]

### Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing of Proposed Rule Change Amending the Eighth Amended and Restated Operating Agreement of the Exchange

April 6, 2016.

Pursuant to Section 19(b)(1)<sup>1</sup> of the Securities Exchange Act of 1934 (the "Act")<sup>2</sup> and Rule 19b-4 thereunder,<sup>3</sup> notice is hereby given that, on March 29, 2016, NYSE MKT LLC (the "Exchange" or "NYSE MKT") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to

solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Eighth Amended and Restated Operating Agreement of the Exchange ("Operating Agreement") to (1) change the process for nominating non-affiliated directors; (2) remove a reference to an obsolete category of member; and (3) add references to Designated Market Makers. The proposed rule change is available on the Exchange's Web site at [www.nyse.com](http://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 Exchange proposes to amend the Operating Agreement to (1) change the process for nominating non-affiliated directors; (2) remove a reference to an obsolete category of member; and (3) add references to Designated Market Makers ("DMMs").

###### Process for Nominating Non-Affiliated Directors

Pursuant to the Operating Agreement, at least 20% of the Board of Directors of the Exchange ("Board") is made up of "Non-Affiliated Directors" (commonly referred to as "fair representation directors").<sup>4</sup> Pursuant to Section 2.03(a) of the Operating Agreement, the nominating and governance committee

<sup>4</sup> Pursuant to Section 2.03(a) of the Operating Agreement, Non-Affiliate Directors are persons who are not members of the board of directors of Intercontinental Exchange, Inc. ("ICE"). A person may not be a Non-Affiliate Director unless he or she is free of any statutory disqualification, as defined in Section 3(a)(39) of the Exchange Act. Non-Affiliate Directors need not be independent.

("NGC") of the board of directors of ICE, the indirect parent of the Exchange, nominates the candidates for Non-Affiliated Directors, who are then elected by NYSE Group, as the sole member of the Exchange. The Exchange proposes to amend Section 2.03(a) to have the Director Candidate Recommendation Committee ("DCRC") of the Exchange assume the role currently played by the ICE NGC, and to make a conforming change to Section 2.03(h)(i). In addition, if the Member Organizations endorse a petition candidate for Non-Affiliate Director, pursuant to Section 2.03(a)(iv) the ICE NGC makes the determination of whether the person is eligible.<sup>5</sup> The Exchange proposes to amend Section 2.03(a)(iv) to have the Exchange make such determination instead of the ICE NGC.

Currently, the nomination by the ICE NGC is the final step in the process for electing a Non-Affiliated Director. First, the DCRC recommends a candidate, whose name then is announced to the Exchange's Member Organizations. The Member Organizations may propose alternate candidates by petition. If there are no petition candidates, the DCRC recommends its candidate to the ICE NGC. If petition candidates are proposed, the ICE NGC makes the determination of whether the candidates are eligible, and then all of the eligible candidates are submitted to the Member Organizations for a vote. The DCRC recommends to the ICE NGC the candidate receiving the highest number of votes. The ICE NGC is obligated to designate the DCRC-recommended candidate as the nominee, and NYSE Group is obligated to elect him or her as a Non-Affiliated Director.

The Exchange believes obligating the ICE NGC to nominate the candidates for Non-Affiliated Directors based on the DCRC's unalterable recommendation is neither necessary nor meaningful. Pursuant to Section 2.03(a)(iii) the ICE NGC is obligated to designate whomever the DCRC recommends or, if there is a petition candidate, whomever emerges from the petition process. The ICE NGC does not have any discretion. Removing this unnecessary step would make the NYSE MKT process more efficient.

The Exchange believes that having the Exchange determine whether persons endorsed to be petition candidates are eligible also would be more efficient, as it would not require action from the ICE NGC, thereby removing the possibility

<sup>5</sup> Pursuant to Section 2.02 of the Operating Agreement, "Member Organizations" refers to members and member organizations, as defined in NYSE MKT Rules 18 and 24, respectively.

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 15 U.S.C. 78a.

<sup>3</sup> 17 CFR 240.19b-4.

of any delay in the process. The proposed change would be consistent with the petition process of the Nasdaq Stock Market LLC, in which the exchange determines the eligibility of proposed nominees.<sup>6</sup>

The Exchange believes that the proposed changes will make its process more consistent with the process by which its affiliate, NYSE Arca, Inc. (“NYSE Arca”), designates its fair representation directors, in which the ICE NGC plays no role.<sup>7</sup>

Accordingly, the Exchange proposes to revise Section 2.03(a)(iii)–(v) of the Operating Agreement to amend the process for electing Non-Affiliated Directors. As proposed, the process would be as follows. First, as is currently the case, the DCRC would recommend a candidate, whose name would be announced to the Member Organizations, and the Member Organizations could propose alternate candidates by petition. Second, if there were no petition candidates, the DCRC would nominate the candidate it had previously recommended. If there were petition candidates, the Exchange would make the eligibility determination of petition candidates, all eligible candidates would be submitted to the Member Organizations for a vote, and the DCRC would nominate the candidate receiving the highest number of votes. Finally, NYSE Group would be obligated to elect the DCRC-nominated candidate as a Non-Affiliated Director.

The Exchange would make a conforming change to Section 2.03(h)(i) to state that the DCRC “will be responsible for nominating Non-Affiliate Director Candidates.” Currently, the provision states that the DCRC “will be responsible for recommending Non-Affiliated Director Candidates to the ICE NGC.”

#### Elimination of a Category of DCRC Membership

As noted above, the Operating Agreement requires that the DCRC include representatives from each of four categories of Exchange members. The Exchange proposes to amend Section 2.03(h)(i) of the Operating

Agreement to eliminate from the DCRC representatives of the fourth category, which relates to individuals who are “associated with a Member Organization and spend a majority of their time on the trading floor of the [Exchange] and have as a substantial part of their business the execution of transactions on the trading floor of the [Exchange] for their own account or the account of their Member Organization, but are not registered as a specialist.”<sup>8</sup>

This fourth category describes a class of proprietary traders known as Registered Equity Market Makers (“REMM”) on the former American Stock Exchange LLC, a predecessor of the Exchange. REMMs were floor traders who engaged in on-floor proprietary trading, subject to certain requirements intended to have these members effectively function like market makers, pursuant to the exemption for market makers in Section 11(a)(1)(A) of the Exchange Act.<sup>9</sup> The rules relating to this category of proprietary floor trader were eliminated shortly after the American Stock Exchange LLC was acquired by the NYSE.<sup>10</sup> In addition, NYSE MKT Rule 114, which governed REMMs, was deleted as obsolete in 2012.<sup>11</sup> As a result, there are no Exchange members or member organizations that fall under the fourth category specified in Section 2.03(h)(i) of the Operating Agreement, and so the Exchange proposes to delete references to it as obsolete. The changes would make Section 2.03(h)(i) more consistent with the categories of members of the Committee for Review in Section 2.03(h)(iii).<sup>12</sup>

<sup>8</sup> Representatives from the following three categories would continue to be included on the DCRC: (1) Member organizations that engage in a business involving substantial direct contact with securities customers (commonly referred to as “upstairs firms”), (2) specialists, and (3) floor brokers. The Exchange proposes to add DMMs to category (2), as discussed below. See note 15, *infra*, and accompanying text.

<sup>9</sup> See 17 CFR 240.11a1–5; Division of Market Regulation, United States Securities and Exchange Commission, *Market 2000: An Examination of Current Equity Market Developments* (January 1994) (“Market 2000”), at A V–7, available at <https://www.sec.gov/divisions/marketreg/market2000.pdf>. This class of proprietary traders were known as Registered Competitive Market Makers (“RCMM”) on the NYSE.

<sup>10</sup> See Securities Exchange Act Release No. 58705 (October 1, 2008), 73 FR 58995, 58996 (October 8, 2008) (SR–Amex–2008–63). The NYSE eliminated RCMMs shortly thereafter. See Securities Exchange Act Release No. 60356 (July 21, 2009), 74 FR 37281 (July 28, 2009) (SR–NYSE–2009–08).

<sup>11</sup> See Securities Exchange Act Release No. 68306 (November 28, 2012), 77 FR 71846 (December 4, 2012) (SR–NYSEMKT–2012–68).

<sup>12</sup> See Securities Exchange Act Release No. 77008 (February 1, 2016), 81 FR 6311 (February 5, 2016) (SR–NYSEMKT–2015–106).

#### References to Designated Market Makers

In 2008, the Exchange adopted rules, based on NYSE rules, that transformed specialists in the Exchange’s equity market into DMMs.<sup>13</sup> As a result, market makers on the NYSE MKT equity market are called DMMs and on the NYSE Amex Options LLC (“NYSE Amex Options”) options market are called “specialists.”<sup>14</sup> However, several provisions of the Operating Agreement were not updated, and refer only to specialists. Accordingly, the Exchange proposes to amend Sections 2.02 and 2.03(h)(i) to add references to DMMs.

Section 2.02 of the Operating Agreement provides that the Board has general supervision over Member Organizations and over approved persons in connection with their conduct with or affecting Member Organizations. Section 2.02 further provides that the Board “may disapprove of any member acting as a specialist or odd lot dealer”. The Exchange proposes to add “designated market maker (as defined in Rule 2 of the Company Rules) (‘DMM’)” after “specialist” in Section 2.02.

Section 2.03(h)(i) sets out the categories of individuals that shall be represented on the DCRC. The Exchange proposes to add “or DMM” to the references to “specialist” in categories (ii) and (iii), so that they reference both types of market makers. The changes would be consistent with the categories of members of the Committee for Review in Section 2.03(h)(iii), which refers to both DMMs and specialists.<sup>15</sup>

Finally, the Exchange proposes to make technical and conforming changes to the recitals and signature page of the Operating Agreement.

#### 2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Exchange Act<sup>16</sup> in general, and with Section 6(b)(1)<sup>17</sup> in particular, in that it enables the Exchange to be so organized as to have

<sup>13</sup> See Securities Exchange Act Release Nos. 58705 (Oct. 1, 2008), 73 FR 58995 (Oct. 8, 2008) (SR–Amex–2008–63) (approval order) and 59022 (Nov. 26, 2008), 73 FR 73683 (Dec. 3, 2008) (SR–NYSEALTR–2008–10) (amending equity rules to conform to NYSE New Market Model Pilot rules). See also Securities Exchange Act Release No. 58845 (October 24, 2008), 73 FR 64379, 64381 (October 29, 2008) (SR–NYSE–2008–46) (approving rule change to create NYSE New Market Model Pilot).

<sup>14</sup> The Exchange operates a marketplace for trading options through NYSE Amex Options, a facility of the Exchange. See Rule 2—Equities (i) & (j) (defining DMM) and Rule 927NY (defining specialist).

<sup>15</sup> See note 12, *supra*.

<sup>16</sup> 15 U.S.C. 78f(b).

<sup>17</sup> 15 U.S.C. 78f(b)(1).

<sup>6</sup> See By-Laws of the Nasdaq Stock Market LLC, Art. II, Sec. 1(b) (“The Company may require any proposed nominee to furnish such other information as it may reasonably require to determine the eligibility of such proposed nominee to serve as a Member Representative Director.”).

<sup>7</sup> See Article III, Section 3.02 of the NYSE Arca Bylaws and NYSE Arca Rule 3.2(b)(2). Similarly, the board of directors of The NASDAQ OMX Group, Inc., the sole member of the Nasdaq Stock Market LLC, plays no role in nominating or determining the eligibility of Member Representative Directors. See By-Laws of the Nasdaq Stock Market LLC, Art. II, Sec. 1.

the capacity to be able to carry out the purposes of the Exchange Act and to comply, and to enforce compliance by its exchange members and persons associated with its exchange members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the Exchange.

The proposed change would remove the requirement that the ICE NGC nominate the candidates for Non-Affiliated Directors and have the DCRC nominate the candidates for Non-Affiliated Director directly. This proposed change would remove an unnecessary step in the process of nominating candidates for Non-Affiliated Directors and increase efficiency. In addition, the proposed change would remove the requirement that the ICE NGC make the determination whether persons endorsed to be petition candidates are eligible to be Non-Affiliated Directors, and have the Exchange make such determination instead. By not requiring action from the ICE NGC, the possibility of any resulting delay in the process is removed. For these reasons, the Exchange believes that the proposed rule change would contribute to the orderly operation of the Exchange and would enable the Exchange to be so organized as to have the capacity to carry out the purposes of the Exchange Act and comply and enforce compliance with the provisions of the Exchange Act by its members and persons associated with its members. The Exchange therefore believes that approval of the proposed is consistent with Section 6(b)(1) of the Act.

The Exchange believes that amending the Operating Agreement to remove the requirement that the DCRC include representatives from the fourth category of members would remove a reference to an obsolete category, thereby reducing potential confusion that may result from retaining obsolete references in the Exchange's Operating Agreement. The Exchange believes that eliminating such obsolete references would not be inconsistent with the public interest and the protection of investors because investors will not be harmed and in fact would benefit from increased transparency, thereby reducing potential confusion. Removing such obsolete references will also further the goal of transparency and add clarity to the Exchange's rules.

The Exchange believes that adding references to DMMs enables the Exchange to be so organized as to have the capacity to be able to carry out the purposes of the Exchange Act and to comply, and to enforce compliance by its exchange members and persons

associated with its exchange members, with the provisions of the Exchange Act, the rules and regulations thereunder, and the rules of the Exchange. The proposed addition of a reference to DMMs in Section 2.02 will clarify that the Board has general supervision over all Member Organizations, including the ability to disapprove of any member acting as a DMM, as well as a specialist or odd lot dealer. The proposed addition of references to DMMs in Section 2.03(h)(i) further the goals of Section 6(b)(3) of ensuring fair representation of an exchange's members in the selection of its directors and administration of its affairs by including both types of market makers in the categories of individuals that shall be represented on the DCRC.

The Exchange also believes that this filing furthers the objectives of Section 6(b)(5) of the Exchange Act<sup>18</sup> because the proposed rule change would be consistent with and facilitate a governance and regulatory structure that is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that having the DCRC nominate the candidates for Non-Affiliated Director would remove impediments to and perfect a national market system because the proposed rule change would remove an unnecessary step in the process for nominating candidates for Non-Affiliated Directors and would remove the ICE NGC from making the determination whether persons endorsed to be petition candidates are eligible to be Non-Affiliated Directors. By not requiring action from the ICE NGC, the possibility of any resulting delay in the process is removed. The Exchange believes that the proposed rule change is therefore consistent with and facilitates a governance and regulatory structure that furthers the objectives of Section 6(b)(5) of the Act.

#### *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 Exchange Act.

The proposed rule change is not intended to address competitive issues but rather is concerned solely with the administration and functioning of the Exchange and its board of directors.

#### *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**

Within 45 days of the date of publication of this notice in the **Federal Register** or up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

#### **IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

##### *Electronic Comments*

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-NYSEMK-2016-26 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-NYSEMK-2016-26. 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

<sup>18</sup> 15 U.S.C. 78f(b)(5).

communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEMKT-2016-26, and should be submitted on or before May 3, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>19</sup>

**Robert W. Errett,**

*Deputy Secretary.*

[FR Doc. 2016-08300 Filed 4-11-16; 8:45 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-77539; File No. SR-NYSEARCA-2016-49]

### Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change to Rule 6.64 With Respect to Opening Trading in an Options Series

April 6, 2016.

Pursuant to Section 19(b)(1)<sup>1</sup> of the Securities Exchange Act of 1934 (the "Act")<sup>2</sup> and Rule 19b-4 thereunder,<sup>3</sup> notice is hereby given that, on March 23, 2016, 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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

#### I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes changes to Rule 6.64 (OX Opening Process) with respect to opening trading in an options series. The proposed rule change is available on the Exchange's Web site at [www.nyse.com](http://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 Exchange is proposing changes to Rule 6.64 with respect to opening trading in an option series as described below.

###### Opening Process

Rule 6.64 describes the process pursuant to which OX ("OX System")<sup>4</sup> opens an option series. Paragraphs (b) and (c) of Rule 6.64 provide that, after the primary market for the underlying security disseminates the opening trade or opening quote, the OX System then conducts an "Auction Process" to open a series whereby the OX System determines a single price at which a series may be opened by looking to: (i) The midpoint of the initial uncrossed NBBO disseminated by the Options Price Reporting Authority ("OPRA"), if any, or (ii) the midpoint of the best quotes or orders in the OX Book. If the bid-ask differential for a series is not within an acceptable range, the OX System will not conduct an Auction Process.<sup>5</sup> For purposes of this rule, the acceptable range means the bid-ask

differential guidelines specified in Rule 6.37(b)(1)(A)-(E).<sup>6</sup> Assuming the bid-ask differential is within the acceptable range, the OX System matches up orders and quotes based on price-time priority<sup>7</sup> and executes the orders that are matched at the midpoint pricing.<sup>8</sup>

Any orders in the OX System that are not executed in the Auction Process become eligible for the Core Trading Session immediately after the conclusion of the Auction Process. If the OX System does not open a series with an Auction Process, the OX System shall open the series for trading after receiving notification of an initial NBBO disseminated by OPRA for the series or on a Market Maker quote, provided that the bid-ask differential does not exceed the bid-ask differential specified under Rule 6.37A(b)(4).<sup>9</sup>

###### Proposed Modifications to the Opening Process

First, the Exchange proposes to change Rule 6.64(b) regarding how the OX System determines when to start the Auction Process. Current paragraph (b) of the Rule provides that "[a]fter the primary market for the underlying security disseminates the opening trade or the opening quote, the related option series will be opened automatically." However, because it is possible that either an opening quote or opening trade alone may not accurately reflect the state of the market, the Exchange proposes to specify that an option series will be opened automatically, "once the primary market for the underlying security disseminates a quote and a trade that is at or within the quote."<sup>10</sup> The Exchange believes the proposed change makes clear that the Exchange would only open a series automatically after it receives a quote in the underlying security *and* a trade in that security at or between the disseminated quote rather than simply upon receipt of

<sup>6</sup> Rule 6.37(b)(1). The bid-ask guidelines specified in Rule 6.37(b)(1)(A)-(E) that are required to open a series are narrower than the \$5 wide bid-ask differential for options traded on OX during Core Trading Hours.

<sup>7</sup> Orders will have priority over Market Maker quotes at the same price. See Rule 6.64(b)(B).

<sup>8</sup> See Rule 6.64(b)(B). The Exchange notes that the word Order appears capitalized in this paragraph and, because it is not a defined term, the Exchange proposes the non-substantive change of eliminating the capitalization.

<sup>9</sup> See Rule 6.37A(b)(4). See Rule 6.37(b)(5) [sic] provides that options traded on OX during Core Trading Hours may be quoted with a difference not to exceed \$5 between the bid and offer regardless of the price of the bid.

<sup>10</sup> See proposed Rule 6.64 (b). The Exchange also proposes to clarify that "[a]t or after 9:30 a.m. Eastern Time," *i.e.*, when the market opens, the Exchange would initiate the Opening Process for all series associated with the underlying security. See *id.*

<sup>19</sup> 17 CFR 200.30-3(a)(12).

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 15 U.S.C. 78a.

<sup>3</sup> 17 CFR 240.19b-4.

<sup>4</sup> The term "OX" refers to the Exchange's electronic order delivery, execution and reporting system for designated option issues through which orders and quotes of Users are consolidated for execution and/or display. See Rule 6.1A(a)(13) (defining "OX").

<sup>5</sup> The Auction bid-ask differentials are known in common parlance as "legal-width quotes."

either an “opening trade or opening quote.” The Exchange believes that waiting to open trading in an option series until there has been both a disseminated quote and trade in the underlying security would help to augment the Auction Process by ensuring that an underlying security has been opened pursuant to a robust price discovery process before opening the overlying options for trading. The Exchange believes that the proposed change would provide market participants with greater certainty as to the true state of the market at the opening of the trading day and should lead to more accurate prices on the Exchange.<sup>11</sup>

Next, the Exchange proposes to modify Rule 6.64(b)(E), which currently provides, in relevant part, that “[i]f the OX System does not open a series with an Auction Process, the OX System shall open the series for trading after receiving notification of an initial NBBO disseminated by OPRA for the series or on a Market Maker quote.”<sup>12</sup> However, the Exchange has determined that it would no longer open on a local Market Maker quote but would require that Market Maker quotes, like the NBBO, come from OPRA. Thus, the Exchange proposes to open after receiving an “initial uncrossed NBBO from ORRA” and to delete rule text related to opening on a Market Maker quote.<sup>13</sup> The Exchange notes that OPRA disseminates to each exchange the NBBO as well as the top of book for each exchange, such that the Exchange’s market maker quote would be disseminated back to the Exchange as the BBO—and could be, but is not necessarily, the NBBO. Because OPRA disseminates this information to all exchanges at the same time, the Exchange believes the proposal to open only after receiving an uncrossed NBBO from OPRA would eliminate any ambiguity as to the source of the information used to open each series and should lead to more accurate prices on the Exchange.

In connection with the proposed changes to Rule 6.64(b), the Exchange likewise proposes to strike from Rule

<sup>11</sup> The Exchange notes that it would not open, for example if the first disseminated quote in the underlying security is \$50.50 bid, \$50.75 ask, and the first trade in the underlying had been executed for \$50.00. The Exchange would, however open if the first trade in the underlying was \$50.50.

<sup>12</sup> See Rule 6.64(b)(E).

<sup>13</sup> See proposed Rule 6.64(b)(E) (providing that “[i]f the OX System does not open a series with an Auction Process, the OX System shall open the series for trading after receiving notification of an initial uncrossed NBBO disseminated by OPRA for the series, provided that the bid-ask differential does not exceed the bid-ask differential specified under Rule 6.37A(b)(4).”

6.64(c) reference to “the midpoint of the best quote bids and quote offers in the OX Book” as it relates to the Exchange determining the opening price for options issues designated for trading on the OX System.<sup>14</sup> The Exchange believes this conforming change is necessary given that the Exchange would no longer open solely on a Market Maker quote and therefore this information would not form the basis of the opening price of a series. As proposed, the opening price of a series would be the price “at which the greatest number of contracts will trade at or nearest to the midpoint of the initial uncrossed NBBO disseminated by OPRA.”<sup>15</sup> The Exchange believes this change adds transparency and internal consistency to the rule text.

Finally, the Exchange proposes new paragraph (F) to Rule 6.64(b) to provide the Exchange with discretion to deviate from the standard Opening Process where it is necessary in the interests of a fair and orderly market.<sup>16</sup> This proposed rule change is based on the rules of other options exchanges.<sup>17</sup> Similar to how other markets operate, the Exchange believes it may be appropriate, in the interest of a fair and orderly market, to open trading even if the conditions specified in Rule 6.64 are not met. For example, if the primary market is unable to open due to a systems or technical issue, but trading in the underlying security is otherwise unaffected, the Exchange believes it would be appropriate to open trading in any options series overlying such securities. Further, proposed Rule 6.64(b)(F) would provide the Exchange with discretion to manage the Opening Process in the event of unanticipated circumstances occurring around 9:30 a.m. Eastern Time or a halt being lifted.

## 2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section

<sup>14</sup> Current Rule 6.64(c) provides, in relevant part, that the opening price of a series will be the price “at which the greatest number of contracts will trade at or nearest to the midpoint of the initial uncrossed NBBO disseminated by OPRA, if any, or the midpoint of the best quote bids and quote offers in the OX Book.”

<sup>15</sup> See proposed Rule 6.64(c).

<sup>16</sup> See proposed Rule 6.64(b)(F) (providing that “[t]he Exchange may deviate from the standard manner of the Auction Process, including adjusting the timing of the Auction Process in any option class, when it believes it is necessary in the interests of a fair and orderly market”).

<sup>17</sup> See e.g., BATS Exchange, Inc. (“BATS”) Rule 21.7(c) (Market Opening Procedures) (“The Exchange may deviate from the standard manner of the Opening Process, including adjusting the timing of the Opening Process in any option class, when it believes it is necessary in the interests of a fair and orderly market”).

6(b)<sup>18</sup> of the Securities Exchange Act of 1934 (the “Act”), in general, and furthers the objectives of Section 6(b)(5),<sup>19</sup> in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

Specifically, the proposed change to Rule 6.64(b) would clarify that the Exchange would only open a series automatically after it receives a quote in the underlying security and a trade in that security at or between the disseminated quote—as opposed to automatically opening on either an opening quote or an opening trade alone per the current rule text, which may not always accurately reflect the state of the market. The Exchange believes this added transparency would promote just and equitable principles of trade and remove impediments to, and perfect the mechanism of, a free and open market and a national market system to the benefit of market participants. Further, the Exchange believes that waiting to open trading in an option series until there has been both a disseminated quote and trade in the underlying security would protect investors and the public interest because it would help to augment the Auction Process by ensuring that an underlying security has been opened pursuant to a robust price discovery process before opening the overlying options for trading. Moreover, this proposed change would promote just and equitable principles of trade to the benefit of investors and the public interest because it would provide market participants with greater certainty as to the true state of the market at the opening of the trading day and should lead to more accurate prices on the Exchange.

The Exchange also believes that specifying that, to open a series, the Exchange would require an initial uncrossed NBBO disseminated by OPRA would promote just and equitable principles of trade as the change is designed to protect investors and the public interest. The Exchange notes that OPRA disseminates to each exchange the NBBO as well as the top of book for each exchange, such that the Exchange’s market maker quote would be disseminated back to the Exchange as the BBO—and could be, but is not necessarily, the NBBO. Because OPRA disseminates this information to all

<sup>18</sup> 15 U.S.C. 78f(b).

<sup>19</sup> 15 U.S.C. 78f(b)(5).

exchanges at the same time, the Exchange believes the proposal to open only after receiving an uncrossed NBBO from OPRA would eliminate any ambiguity as to the source of the information for each series and should lead to more accurate prices on the Exchange.

Similarly, the Exchange believes the conforming change to Rule 6.64(c), which strikes reference to quote bids and quote offers in the OX Book for purposes of determining an opening price, likewise would promote just and equitable principles of trade as it would add transparency and internal consistency to Exchange rules, which would make them easier for market participants to navigate.

Finally, the Exchange believes the proposal to permit the Exchange to open options trading when such opening is in the interests of a fair and orderly market (even if the conditions set forth in the rule are not met), is consistent with the protection of investors and the public interest because the proposed changes would allow the Exchange to open trading in options contracts in a fair and orderly manner. Specifically, the Exchange believes that the proposed changes would reduce potential delays in opening an option series that may prevent the Exchange from displaying and/or routing orders on its Consolidated Book and may also prevent the Exchange from disseminating a protected quote that draws trading interest from other options markets. Thus, the Exchange believes that the proposed changes would allow the Exchange to open options series faster and more efficiently, thereby reducing any delay in execution of orders on the Exchange that may be unnecessary and harmful to market participants. The Exchange also notes that this proposed rule change is based on the rules of other options exchanges.<sup>20</sup>

#### *B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change is not designed to address any competitive issue but rather to add specificity and transparency to Exchange rules, thereby reducing confusion and making the Exchange's rules easier to understand and navigate. The Exchange believes that the proposed rule change would serve to promote regulatory clarity and

consistency, thereby reducing burdens on the marketplace and facilitating investor protection.

#### *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**

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

- (A) By order approve or disapprove the proposed rule change, or
- (B) Institute proceedings to determine whether the proposed rule change should be disapproved.

#### **IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

##### *Electronic Comments*

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to [rule-comments@sec.gov](mailto:rule-comments@sec.gov). Please include File Number SR-NYSEARCA-2016-49 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-NYSEARCA-2016-49. 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 the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR-NYSEARCA-2016-49 and should be submitted on or before May 3, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>21</sup>

**Robert W. Errett,**  
*Deputy Secretary.*

[FR Doc. 2016-08303 Filed 4-11-16; 8:45 am]

**BILLING CODE 8011-01-P**

## **SMALL BUSINESS ADMINISTRATION**

**[Disaster Declaration #14675 and #14676]**

### **Texas Disaster Number TX-00465**

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Amendment 2.

**SUMMARY:** This is an amendment of the Presidential declaration of a major disaster for the State of Texas (FEMA-4266-DR), dated 03/19/2016.

*Incident:* Severe storms, tornadoes, and flooding.

*Incident Period:* 03/07/2016 and continuing through 03/29/2016.

*Effective Date:* 03/29/2016.

*Physical Loan Application Deadline Date:* 05/18/2016.

*EIDL Loan Application Deadline Date:* 12/19/2016.

**ADDRESSES:** Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

**FOR FURTHER INFORMATION CONTACT:** A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

**SUPPLEMENTARY INFORMATION:** The notice of the President's major disaster

<sup>20</sup> See *supra* n. 17.

<sup>21</sup> 17 CFR 200.30-3(a)(12).



declaration for the State of Texas, dated 03/19/2016 is hereby amended to establish the incident period for this disaster as beginning 03/07/2016 and continuing through 03/29/2016.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59008)

**James E. Rivera,**

*Associate Administrator for Disaster Assistance.*

[FR Doc. 2016-08308 Filed 4-11-16; 8:45 am]

**BILLING CODE 8025-01-P**

**SMALL BUSINESS ADMINISTRATION**

[Disaster Declaration #14690 and #14691]

**District of Columbia Disaster #DC-00007**

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Notice.

**SUMMARY:** This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the District of Columbia (FEMA-4260-DR), dated 04/01/2016.

*Incident:* Snowstorm.

*Incident Period:* 01/22/2016 through 01/23/2016.

*Effective date:* 04/01/2016.

*Physical Loan Application Deadline Date:* 05/31/2016.

*Economic Injury (EIDL) Loan Application Deadline Date:* 01/03/2017.

**ADDRESSES:** Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

**FOR FURTHER INFORMATION CONTACT:** A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that as a result of the President's major disaster declaration on 04/01/2016, Private Non-Profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

*Primary Area:* District of Columbia.

The Interest Rates are:

	Percent
For Physical Damage:	

	Percent
Non-Profit Organizations With Credit Available Elsewhere ...	2.625
Non-Profit Organizations Without Credit Available Elsewhere .....	2.625
<i>For Economic Injury:</i>	
Non-Profit Organizations Without Credit Available Elsewhere .....	2.625

The number assigned to this disaster for physical damage is 14690B and for economic injury is 14691B

(Catalog of Federal Domestic Assistance Numbers 59008)

**Lisa Lopez-Suarez,**

*Acting Associate Administrator for Disaster Assistance.*

[FR Doc. 2016-08310 Filed 4-11-16; 8:45 am]

**BILLING CODE 8025-01-P**

**SMALL BUSINESS ADMINISTRATION**

**Reporting and Recordkeeping Requirements Under OMB Review**

**AGENCY:** Small Business Administration.

**ACTION:** 30-Day notice.

**SUMMARY:** The Small Business Administration (SBA) is publishing this notice to comply with requirements of the Paperwork Reduction Act (PRA) (44 U.S.C. Chapter 35), which requires agencies to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission. This notice also allows an additional 30 days for public comments.

**DATES:** Submit comments on or before May 12, 2016.

**ADDRESSES:** Comments should refer to the information collection by name and/or OMB Control Number and should be sent to: *Agency Clearance Officer*, Curtis Rich, Small Business Administration, 409 3rd Street SW., 5th Floor, Washington, DC 20416; and *SBA Desk Officer*, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:** Curtis Rich, Agency Clearance Officer, (202) 205-7030 [curtis.rich@sba.gov](mailto:curtis.rich@sba.gov).

*Copies:* A copy of the Form OMB 83-1, supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

**SUPPLEMENTARY INFORMATION:** Information collection is needed to

ensure that Microloan Program activity meets the statutory goals of assisting mandated target market. The information is used by the reporting participants and the SBA to assist with portfolio management, risk management, loan servicing oversight and compliance, data management and understanding of short and long term trends and development of outcome measures.

**Solicitation of Public Comments**

SBA is requesting comments on (a) Whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

*Title:* Microloan Program Electronic Reporting System (MPERS).

*Description of Respondents:* SBA reporting participants in the Microloan Program.

*Form Number:* N/A.

*Estimated Annual Responses:* 6,240.

*Estimated Annual Hour Burden:* 3,080.

**Curtis B. Rich,**

*Management Analyst.*

[FR Doc. 2016-08315 Filed 4-11-16; 8:45 am]

**BILLING CODE 8025-01-P**

**SMALL BUSINESS ADMINISTRATION**

[Disaster Declaration #14685 and #14686]

**Mississippi Disaster Number MS-00084**

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Amendment 1.

**SUMMARY:** This is an amendment of the Presidential declaration of a major disaster for the State of Mississippi (FEMA-4268-DR), dated 03/25/2016.

*Incident:* Severe storms and flooding.  
*Incident Period:* 03/09/2016 and continuing.

*Effective Date:* 03/31/2016.

*Physical Loan Application Deadline Date:* 05/24/2016.

*EIDL Loan Application Deadline Date:* 12/27/2016.

**ADDRESSES:** Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

**FOR FURTHER INFORMATION CONTACT:** Alan Escobar, Office of Disaster

Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

**SUPPLEMENTARY INFORMATION:** The notice of the Presidential disaster declaration for the State of MISSISSIPPI, dated 03/25/2016 is hereby amended to include the following areas as adversely affected by the disaster:

*Primary Counties: (Physical Damage and Economic Injury Loans):*

Clarke, Forrest, Greene, Jones, Marion, Panola, Perry, Quitman, Sunflower, Tunica, Wayne.

*Contiguous Counties: (Economic Injury Loans Only):*

Mississippi: Covington, Desoto, George, Jasper, Jefferson Davis, Lafayette, Lamar, Lauderdale, Lawrence, Leflore, Newton, Pearl River, Smith, Stone, Tate, Walthall, Yalobusha.

Alabama: Choctaw, Mobile, Washington.

Arkansas: Crittenden, Lee.

Louisiana: Washington.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59008)

**James E. Rivera,**

*Associate Administrator for Disaster Assistance.*

[FR Doc. 2016-08309 Filed 4-11-16; 8:45 am]

**BILLING CODE 8025-01-P**

## DEPARTMENT OF STATE

[Public Notice: 9514]

### Notice of Information Collection Under OMB Emergency Review: Adoptive Family Relief Act Refund Application

**ACTION:** Notice of request for emergency OMB approval and public comment.

**SUMMARY:** The Department of State has submitted the information collection request described below to the Office of Management and Budget (OMB) for review and approval in accordance with the emergency review procedures of the Paperwork Reduction Act of 1995 (5 CFR 1320.13). The purpose of this notice is to allow for public comment from all interested individuals and organizations. Emergency review and approval of this collection has been requested from OMB by April 29, 2016. If granted, the emergency approval is only valid for 180 days. The Department plans to follow this emergency request with a submission for a 3 year approval through OMB's normal PRA clearance process (5 CFR 1320.10).

**ADDRESSES:** Direct any comments on this emergency request to both the

Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB) and to the Legislation and Regulation Division in the Department of State's Visa Office.

All public comments must be received by April 25, 2016. You may submit comments to OMB by the following methods:

- *Email:* [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). You must include the DS form number, information collection title, and OMB control number in the subject line of your message.

- *Fax:* 202-395-5806. Attention: Desk Officer for Department of State.

You may submit comments to the Visa Office by the following methods:

- *Web:* Persons with access to the Internet may comment on this notice by going to [www.Regulations.gov](http://www.Regulations.gov). You can search for the document by entering "Docket Number: DOS-2016-0020" in the Search field. Then click the "Comment Now" button and complete the comment form.

- *Email:* [PRA\\_BurdenComments@state.gov](mailto:PRA_BurdenComments@state.gov). You must include *Emergency Submission Comment on "information collection title"* in the subject line of your message.

#### FOR FURTHER INFORMATION CONTACT:

Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Taylor Mauck, who may be reached at 202-485-7635 or at [PRA\\_BurdenComments@state.gov](mailto:PRA_BurdenComments@state.gov).

#### SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Adoptive Family Relief Act Refund Application.

- *OMB Control Number:* None.

- *Type of Request:* Emergency Review.

- *Originating Office:* CA/VO/L/R.

- *Form Number:* DS-7781.

- *Respondents:* Immigrant Visa Petitioners.

- *Estimated Number of Respondents:* 600.

- *Estimated Number of Responses:* 600.

- *Average Time per Response:* 5 Minutes.

- *Total Estimated Burden Time:* 50 Hours.

- *Frequency:* Once.

- *Obligation to respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.

- Evaluate the accuracy of our estimate of the time and cost burden of this proposed collection, including the validity of the methodology and assumptions used.

- Enhance the quality, utility, and clarity of the information to be collected.

- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

#### Abstract of Proposed Collection

The Adoptive Family Relief Act (Pub. L. 114-70) amended section 221(c) of the Immigration and Nationality Act (INA), 8 U.S.C. 1201(c), to allow for the waiver or refund certain immigrant visa fees for a lawfully adopted child, or a child coming to the United States to be adopted by a United States citizen, subject to criteria prescribed by the Secretary of State. Over 350 American families have successfully adopted children from the Democratic Republic of the Congo. However, since September 25, 2013, they have not been able to bring their adoptive children home to the United States because the Democratic Republic of the Congo suspended the issuance of "exit permits" for these children. As the permit suspension drags on, however, American families are repeatedly paying visa renewal and related fees, while also continuing to be separated from their adopted children.

The waiver or refund provides support and relief to American families seeking to bring their adoptive children from the Democratic Republic of Congo to the United States, and would also provide relief to similarly situated adoptive families should barriers arise in other countries in the future. See 161 Cong. Rec. S2796-01.

This form will collect information to determine the extra fees these families have paid and refund them in accordance with the Adoptive Family Relief Act. This is an emergency collection in order to immediately alleviate the financial burden on families who need multiple visas and those families are still waiting for refunds.

#### Methodology

The form DS-7781 will be hosted on the Department of State Web site to be

printed, filled out, and eventually sent to the Consular Section where the adoption case was originally processed.

Dated: March 21, 2016.

**Edward Ramotowski,**

*Deputy Assistant Secretary, Bureau of Consular Affairs, Department of State.*

[FR Doc. 2016-08391 Filed 4-11-16; 8:45 am]

**BILLING CODE 4710-06-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

[Summary Notice No. PE-2016-0034]

#### Petition for Exemption; Summary of Petition Received; The Dobbins Company

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice.

**SUMMARY:** This notice contains a summary of a petition seeking relief from specified requirements of title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

**DATES:** Comments on this petition must identify the petition docket number and must be received on or before May 2, 2016.

**ADDRESSES:** Send comments identified by docket number FAA-2015-0060 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

- *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* Fax comments to Docket Operations at 202-493-2251.

*Privacy:* In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal

information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

*Docket:* Background documents or comments received may be read at <http://www.regulations.gov> at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Dan Ngo (202) 267-4264 Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on April 1, 2016.

**James M. Crotty,**

*Acting Director, Office of Rulemaking.*

#### Petition for Exemption

*Docket No.:* FAA-2015-0060.

*Petitioner:* The Dobbins Company.

*Section(s) of 14 CFR Affected:*

§§ 91.407 (a)(1); 91.405 (a); 91.151 (a)(1); 91.121; 91.119 (c); 91.7 (a); 61.113 (a); 61.23 (a)(1); 61.101 (e)(4)(5); 61.315 (a); 91.417 (a)(b); 91.409 (a)(1)(2).

*Description of Relief Sought:* The petitioner requests to conduct commercial UAS operations within 200 feet and under bridges.

[FR Doc. 2016-08313 Filed 4-11-16; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

[Summary Notice No. PE-2016-36]

#### Petition for Exemption; Summary of Petition Received; Martin UAV

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice.

**SUMMARY:** This notice contains a summary of a petition seeking relief from specified requirements of title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

**DATES:** Comments on this petition must identify the petition docket number and must be received on or before May 2, 2016.

**ADDRESSES:** Send comments identified by docket number FAA-2015-5644 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

- *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* Fax comments to Docket Operations at 202-493-2251.

*Privacy:* In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

*Docket:* Background documents or comments received may be read at <http://www.regulations.gov> at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Dan Ngo, (202) 267-4264. 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

**James M. Crotty,**

*Acting Director, Office of Rulemaking.*

#### Petition for Exemption

*Docket No.:* FAA-2015-5644.

*Petitioner:* Martin UAV.

*Section(s) of 14 CFR Affected:* Part 21, Subpart H; §§ 45.23(b); 45.27(a); 61.113; 91.7(a); 91.9(b)(2); 91.9(c); 91.103(b)(2); 91.109(a); 91.119(c); 91.121; 91.151(a); 91.203 (a) & (b); 91.405(a); 91.407(a)(1); 91.409(a)(1) & (2); 91.417 (a) & (b).

*Description of Relief Sought:* The petitioner is requesting relief to conduct commercial operations, including

training, with the Bat 4 and V-Bat, both of which are heavier than 55 pounds, as well as the SuperBat.

[FR Doc. 2016-08314 Filed 4-11-16; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

[Summary Notice No. PE-2016-0035]

#### Petition for Exemption; Summary of Petition Received; Invictus Technical Solutions LLC

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice.

**SUMMARY:** This notice contains a summary of a petition seeking relief from specified requirements of title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

**DATES:** Comments on this petition must identify the petition docket number and must be received on or before May 2, 2016.

**ADDRESSES:** Send comments identified by docket number FAA-2015-4805 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

- *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* Fax comments to Docket Operations at 202-493-2251.

*Privacy:* In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

*Docket:* Background documents or comments received may be read at <http://www.regulations.gov> at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Joshua Parker (202) 267-1538, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

**James M. Crotty,**

*Acting Director, Office of Rulemaking.*

#### Petition for Exemption

*Docket No.:* FAA-2015-4805.

*Petitioner:* Invictus Technical Solutions LLC.

*Section(s) of 14 CFR Affected:*

§§ 91.417(a)(b); 91.409(a)(1)(2); 91.407(a)(1); 91.405(a); 91.151(a)(1); 91.121; 91.119(c); 91.7(a); 61.315(a); 61.113(a); 61.101(e)(4)(5); 61.23(a)(c).

*Description of Relief Sought:* The petitioner is requesting release of objects/dispensing of materials by small, unmanned aircraft in commercial operations only within U.S. airspace.

[FR Doc. 2016-08320 Filed 4-11-16; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

[Summary Notice No. PE-2016-0037]

#### Petition for Exemption; Summary of Petition Received; AeroLogix Consulting Inc.

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice.

**SUMMARY:** This notice contains a summary of a petition seeking relief from specified requirements of title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

**DATES:** Comments on this petition must identify the petition docket number and must be received on or before May 2, 2016.

**ADDRESSES:** Send comments identified by docket number FAA-2015-0094 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

- *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* Fax comments to Docket Operations at 202-493-2251.

*Privacy:* In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

*Docket:* Background documents or comments received may be read at <http://www.regulations.gov> at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Dan Ngo (202) 267-4264, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on April 1, 2016.

**James M. Crotty,**

*Acting Director, Office of Rulemaking.*

#### Petition for Exemption

*Docket No.:* FAA-2015-0094.

*Petitioner:* AeroLogix Consulting Inc.

*Section(s) of 14 CFR Affected:* part 21, Subpart H, §§ 45.23; 45.25; 45.29; 61.113; 61.133; 91.417(a)(b); 91.409(a)(1)(2); 91.407(a)(1); 91.405(a); 91.307(a); 91.151(a)(1); 91.121; 91.9(b)(2)(c); 91.7(a); 91.203(a)(1); 91.207(a)(1);

*Description of Relief Sought:* The petitioner is seeking relief to amend Exemption No. 11370 to operate up to

600 feet AGL, within 500 feet from all nonparticipating persons, vessels, vehicles, and structures except during take-off and landing, or on private or controlled-access property without permission from the property owner or authorized representative.

[FR Doc. 2016-08312 Filed 4-11-16; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

[Summary Notice No. PE-2016-38]

#### Petition for Exemption; Summary of Petition Received; Walt Disney Parks and Resorts U.S., Inc.

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice.

**SUMMARY:** This notice contains a summary of a petition seeking relief from specified requirements of title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

**DATES:** Comments on this petition must identify the petition docket number and must be received on or before May 2, 2016.

**ADDRESSES:** Send comments identified by docket number FAA-2015-8680 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

- *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* Fax comments to Docket Operations at 202-493-2251.

*Privacy:* In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to

<http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

*Docket:* Background documents or comments received may be read at <http://www.regulations.gov> at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Dan Ngo, 202-267-4264, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on April 1, 2016.

**James M. Crotty,**

*Acting Director, Office of Rulemaking.*

#### Petition for Exemption

*Docket No.:* FAA-2015-8680.

*Petitioner:* Walt Disney Parks and Resorts U.S., Inc.

*Section(s) of 14 CFR Affected:* Parts 21, 61, and 67; and §§ 91.111, 91.113, 91.119(c), 91.121, 91.151(a), 91.309, 91.311, 91.403(b), 91.405(a), 91.407(a)(1), 91.409(a)(2), and 91.417.

*Description of Relief Sought:* The petitioner is requesting relief in order to fly up to fifty small unmanned aircraft at once within the Disney Resorts' existing no-fly zone at night. The petitioner also seeks relief from the requirement of Certificated Pilots and Medical certificates.

[FR Doc. 2016-08311 Filed 4-11-16; 8:45 a.m.]

BILLING CODE 4910-13-P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

[Summary Notice No. 2016-39]

#### Petition for Exemption; Summary of Petition Received; Cirrus Design Corporation

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice.

**SUMMARY:** This notice contains a summary of a petition seeking relief from specified requirements of title 14 of the Code of Federal Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information

in the summary is intended to affect the legal status of the petition or its final disposition.

**DATES:** Comments on this petition must identify the petition docket number and must be received on or before May 2, 2016.

**ADDRESSES:** Send comments identified by docket number FAA-2015-0534 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.

- *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

- *Fax:* Fax comments to Docket Operations at 202-493-2251.

*Privacy:* In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

*Docket:* Background documents or comments received may be read at <http://www.regulations.gov> at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Paul Pellicano, 404-474-5558, Atlanta Certification Office, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on March 22, 2016.

**Lirio Liu,**

*Director, Office of Rulemaking.*

#### Petition for Exemption

*Docket No.:* FAA-2015-0534.

*Petitioner:* Cirrus Design Corporation.

*Section(s) of 14 CFR Affected:* 23.1419(a).

*Description of Relief Sought:* This exemption request, if granted, would exempt the model SF50 airplane from the 61-knot stall speed with critical ice accretions.

[FR Doc. 2016-08316 Filed 4-11-16; 8:45 am]

BILLING CODE 4910-13-P

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2016-0025]

#### Qualification of Drivers; Exemption Applications; Vision

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of applications for exemptions; request for comments.

**SUMMARY:** FMCSA announces receipt of applications from 11 individuals for exemption from the vision requirement in the Federal Motor Carrier Safety Regulations. They are unable to meet the vision requirement in one eye for various reasons. The exemptions will enable these individuals to operate commercial motor vehicles (CMVs) in interstate commerce without meeting the prescribed vision requirement in one eye. If granted, the exemptions would enable these individuals to qualify as drivers of commercial motor vehicles (CMVs) in interstate commerce.

**DATES:** Comments must be received on or before May 12, 2016. All comments will be investigated by FMCSA. The exemptions will be issued the day after the comment period closes.

**ADDRESSES:** You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA-2016-0025 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.
- *Hand Delivery:* West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

• *Fax:* 1-202-493-2251.

**Instructions:** Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be

posted without change to <http://www.regulations.gov>, including any personal information provided. Please see the Privacy Act heading below for further information.

**Docket:** For access to the docket to read background documents or comments, go to <http://www.regulations.gov> at any time or Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

**Privacy Act:** In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to [www.regulations.gov](http://www.regulations.gov), as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at [www.dot.gov/privacy](http://www.dot.gov/privacy).

**FOR FURTHER INFORMATION CONTACT:** Christine A. Hydock, Chief, Medical Programs Division, (202) 366-4001, [fmcamedical@dot.gov](mailto:fmcamedical@dot.gov), FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64-113, Washington, DC 20590-0001. Office hours are 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds “such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.” FMCSA can renew exemptions at the end of each 2-year period. The 11 individuals listed in this notice have each requested such an exemption from the vision requirement in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting an exemption will achieve the required level of safety mandated by statute.

## II. Qualifications of Applicants

### Jose R. Arroyo

Mr. Arroyo, 46, has had corneal opacity in his right eye since childhood. The visual acuity in his right eye is no light perception, and in his left eye, 20/20. Following an examination in 2015, his optometrist stated, “He had no color defects and in my medical opinion he is able to safely operate a commercial vehicle based in [sic] his vision.” Mr. Arroyo reported that he has driven straight trucks for 12 years, accumulating 540,000 miles. He holds a Class C operator’s license from California. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

### Ronald H. Carey

Mr. Carey, 54, has had decreased vision in his right eye since 2011. The visual acuity in his right eye is 20/200, and in his left eye, 20/25. Following an examination in 2016, his optometrist stated, “In my medical opinion Ronald has sufficient vision to perform the driving tasks required to operate a commercial vehicle.” Mr. Carey reported that he has driven straight trucks for 2 years, accumulating 150,000 miles and tractor-trailer combinations for 27 years, accumulating 1.65 million miles. He holds a Class AM CDL from Pennsylvania. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

### Valentin S. Chernyy

Mr. Chernyy, 51, has complete loss of vision in his left eye due to a traumatic incident in 1986. The visual acuity in his right eye is 20/20, and in his left eye, no light perception. Following an examination in 2015, his optometrist stated, “This certifies in my medical opinion that Valentin Chernyy has sufficient vision in his right eye to perform the driving tasks required to operate a commercial vehicle.” Mr. Chernyy reported that he has driven straight trucks for 14 years, accumulating 980,000 miles. He holds a Class O operator’s license from Nebraska. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

### Danny R. Floyd

Mr. Floyd, 56, has had optic atrophy in his right eye since 2012 due to a traumatic incident. The visual acuity in his right eye is no light perception, and in his left eye, 20/20. Following an examination in 2016, his optometrist

stated, "In my medical opinion, Mr. Floyd's condition is stable and he has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Floyd reported that he has driven tractor-trailer combinations for 30 years, accumulating 2.34 million miles. He holds a Class A CDL from Ohio. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Claudia E. Gerez-Bentacourt*

Ms. Gerez-Bentacourt, 39, has had amblyopia in her right eye since childhood. The visual acuity in her right eye is 20/200, and in her left eye, 20/25. Following an examination in 2015, her ophthalmologist stated, "She was diagnosed with Amblyopia of right eye . . . She is able to perform all driving tasks that [sic] required by commercial vehicle." Ms. Gerez-Bentacourt reported that she has driven tractor-trailer combinations for 6 years, accumulating 420,000 miles. She holds a Class A CDL from Texas. Her driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Andy R. Junod*

Mr. Junod, 62, has had a macular scar in his right eye since childhood. The visual acuity in his right eye is 20/70, and in his left eye, 20/15. Following an examination in 2016, his ophthalmologist stated, "I certify that the visual deficiency of this gentleman is stable and that in my medical opinion, based on the eye exam and his driving record which he verbally gives [sic] to me, that he has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Junod reported that he has driven straight trucks for 5 years, accumulating 120,000 miles and tractor-trailer combinations for 34 years, accumulating 3.74 million miles. He holds a Class AM CDL from Texas. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Roger W. Kerns III*

Mr. Kerns, 22, has had amblyopia in his right eye since childhood. The visual acuity in his right eye is 20/200, and in his left eye, 20/20. Following an examination in 2016 his optometrist stated, "In my medical opinion, Roger W. Kerns III has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Kerns reported that he has driven straight trucks for 2 years, accumulating 1,000 miles and tractor-trailer

combinations for 2 years, accumulating 200,000 miles. He holds a Class A CDL from Iowa. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Gary C. Maxwell*

Mr. Maxwell, 73, has had a pigment epithelia detachment in his left eye in 2000. The visual acuity in his right eye is 20/25, and in his left eye, 20/70. Following an examination in 2015, his ophthalmologist stated, "He has a history of an epiretinal membrane and pigment epithelial detachment of his left eye. He has been driving a commercial vehicle without difficulty for many years, and I feel that he can safely continue to do so without any concerns." Mr. Maxwell reported that he has driven straight trucks for 2 years, accumulating 80,000 miles and tractor-trailer combinations for 40 years, accumulating 12 million miles. He holds a Class A CDL from Ohio. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Scott A. Palmer*

Mr. Palmer, 46, has had amblyopia in his left eye since childhood. The visual acuity in his right eye is 20/20, and in his left eye, 20/300. Following an examination in 2015, his optometrist stated, "In my medical opinion, Scott Palmer has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Palmer reported that he has driven straight trucks for 20 years, accumulating 800,000 miles. He holds a Class B CDL from New York. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Richard G. Roberts*

Mr. Roberts, 82, has had macular degeneration in his right eye since 2008. The visual acuity in his right eye is 20/200, and in his left eye, 20/25. Following an examination in 2015, his ophthalmologist stated, "The patient has been able to operate commercial vehicles safely for many years, including the last seven years after being treated for macular degeneration. There has been no worsening in that time, so I believe that patient can continue to operative [sic] the same types of vehicles at this time and for the foreseeable future." Mr. Roberts reported that he has driven straight trucks for 18 years, accumulating 140,400 miles. He holds a Class A CDL from California. His driving record for the last 3 years shows no crashes and no

convictions for moving violations in a CMV.

*Michael R. Tipton*

Mr. Tipton, 61, has had macular atrophy in his left eye since childhood. The visual acuity in his right eye is 20/30, and in his left eye, 20/200. Following an examination in 2015, his optometrist stated, "In summery Mr. Tipton in my opinion is more than able to meet the requirements visually for operation of a commercial vehicle." Mr. Tipton reported that he has driven tractor-trailer combinations for 15 years, accumulating 20,500 miles. He holds a Class A CDL from Illinois. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

**III. Public Participation and Request for Comments**

FMCSA encourages you to participate by submitting comments and related materials.

*Submitting Comments*

If you submit a comment, please include the docket number for this notice, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov> and put the docket number FMCSA-2016-0025 in the "Keyword" box, and click "Search." When the new screen appears, click on "Comment Now!" button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period. FMCSA may issue a final determination at any time after the close of the comment period.

### Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov> and insert the docket number FMCSA–2016–0025 in the “Keyword” box and click “Search.” Next, click “Open Docket Folder” button and choose the document listed to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

Issued on: April 5, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2016–08358 Filed 4–11–16; 8:45 am]

BILLING CODE 4910–EX–P

## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2016–0035]

### Qualification of Drivers; Exemption Applications; Diabetes Mellitus

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of applications for exemptions; request for comments.

**SUMMARY:** FMCSA announces receipt of applications from 46 individuals for exemption from the prohibition against persons with insulin-treated diabetes mellitus (ITDM) operating commercial motor vehicles (CMVs) in interstate commerce. If granted, the exemptions would enable these individuals with ITDM to operate CMVs in interstate commerce.

**DATES:** Comments must be received on or before May 12, 2016.

**ADDRESSES:** You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2016–0035 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.

- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200

New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

- *Fax:* 1–202–493–2251.

*Instructions:* Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. Please see the Privacy Act heading below for further information.

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**FOR FURTHER INFORMATION CONTACT:** Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, [fmcamedical@dot.gov](mailto:fmcamedical@dot.gov), FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–113, Washington, DC 20590–0001. Office hours are 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays.

### SUPPLEMENTARY INFORMATION:

#### I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds “such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.” The statute also allows the Agency to renew exemptions at the end of the 2-year period. The 46 individuals listed in this notice have recently requested such an exemption from the diabetes prohibition

in 49 CFR 391.41(b) (3), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by statute.

### II. Qualifications of Applicants

#### William M. Adams

Mr. Adams, 50, has had ITDM since 2009. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Adams understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Adams meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from South Carolina.

#### Gerald L. Beideck

Mr. Beideck, 67, has had ITDM since 1985. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Beideck understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Beideck meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator’s license from Oregon.

#### John J. Bizanos

Mr. Bizanos, 54, has had ITDM since 2012. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in



the last 5 years. His endocrinologist certifies that Mr. Bizanos understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Bizanos meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from New York.

*Joseph T. Bohnert*

Mr. Bohnert, 82, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Bohnert understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Bohnert meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

*Phillip J. Boruszewski*

Mr. Boruszewski, 47, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Boruszewski understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Boruszewski meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Illinois.

*Harold F. Braithwaite*

Mr. Braithwaite, 56, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in

impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Braithwaite understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Braithwaite meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Ohio.

*Kenneth H. Brown*

Mr. Brown, 73, has had ITDM since 2010. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Brown understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Brown meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from New York.

*Alfred S. Church, Jr.*

Mr. Church, 58, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Church understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Church meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from Indiana.

*James R. Conley*

Mr. Conley, 49, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no

severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Conley understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Conley meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Indiana.

*Irvin L. Davis*

Mr. Davis, 51, has had ITDM since 2012. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Davis understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Davis meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Virginia.

*Richard J. Dudzenski*

Mr. Dudzenski, 34, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Dudzenski understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Dudzenski meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

*William M. Dutton*

Mr. Dutton, 56, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Dutton understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Dutton meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from North Dakota.

*Richard W. Favier*

Mr. Favier, 64, has had ITDM since 2012. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Favier understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Favier meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from Connecticut.

*Richard G. Fiscus, Jr.*

Mr. Fiscus, 57, has had ITDM since 1990. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Fiscus understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Fiscus meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that

he does not have diabetic retinopathy. He holds an operator's license from Massachusetts.

*Donald Fleming*

Mr. Fleming, 56, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Fleming understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Fleming meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Illinois.

*Sergio A. Garza*

Mr. Garza, 58, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Garza understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Garza meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Illinois.

*Stanley L. Gear*

Mr. Gear, 54, has had ITDM since 2004. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Gear understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Gear meets the requirements

of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Missouri.

*Ira S. Gelb*

Mr. Gelb, 55, has had ITDM since 2005. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Gelb understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Gelb meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class C CDL from Massachusetts.

*Raymond C. Hartill*

Mr. Hartill, 64, has had ITDM since 2005. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hartill understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hartill meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Washington.

*Todd E. Himebauch*

Mr. Himebauch, 55, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Himebauch understands

diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Himebauch meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from Illinois.

*John R. Hofmann, Jr.*

Mr. Hofmann, 47, has had ITDM since 1988. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hofmann understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hofmann meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from Illinois.

*Matthew E. Ingham*

Mr. Ingham, 45, has had ITDM since 1989. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Ingham understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Ingham meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Washington.

*Grant L. Jensen*

Mr. Jensen, 52, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or

resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Jensen understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Jensen meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from South Dakota.

*Victor E. Kaneps*

Mr. Kaneps, 58, has had ITDM since 1965. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Kaneps understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Kaneps meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable proliferative diabetic retinopathy. He holds an operator's license from Colorado.

*Albert J. Laubauskas*

Mr. Laubauskas, 46, has had ITDM since 2003. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Laubauskas understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Laubauskas meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from New Jersey.

*Michael M. Lillie*

Mr. Lillie, 47, has had ITDM since 1996. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Lillie understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Lillie meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class C CDL from Michigan.

*Barrington F. Mahabee*

Mr. Mahabee, 33, has had ITDM since 2001. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Mahabee understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Mahabee meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from New York.

*Brandon T. A. Maines*

Mr. Maines, 26, has had ITDM since 1996. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Maines understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Maines meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy.

He holds an operator's license from Montana.

*Robert J. Marnell*

Mr. Marnell, 29, has had ITDM since 1996. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Marnell understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Marnell meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from Iowa.

*Clayton E. McCoy*

Mr. McCoy, 61, has had ITDM since 2006. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. McCoy understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. McCoy meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Texas.

*Andrew J. Neset*

Mr. Neset, 52, has had ITDM since 1998. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Neset understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Neset meets the requirements

of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from North Dakota.

*Scott A. Newell*

Mr. Newell, 55, has had ITDM since 2001. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Newell understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Newell meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a chauffeur's license from Michigan.

*Braydon D. Paytas*

Mr. Paytas, 22, has had ITDM since 1994. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Paytas understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Paytas meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Utah.

*Edward C. Pisiakowski*

Mr. Pisiakowski, 58, has had ITDM since 2010. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Pisiakowski understands diabetes management and monitoring,

has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Pisiakowski meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Connecticut.

*William J. Pratt*

Mr. Pratt, 46, has had ITDM since 2011. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Pratt understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Pratt meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

*Juan Rangel*

Mr. Rangel, 73, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Rangel understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Rangel meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from California.

*Kyle L. Roy*

Mr. Roy, 31, has had ITDM since 2003. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist

certifies that Mr. Roy understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Roy meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds an operator's license from Ohio.

*Nicola D. Santopietro*

Mr. Santopietro, 61, has had ITDM since 2011. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Santopietro understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Santopietro meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Connecticut.

*Gary R. Silver*

Mr. Silver, 36, has had ITDM since 1998. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Silver understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Silver meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Florida.

*Ryan D. Simmons*

Mr. Simmons, 40, has had ITDM since 2013. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function

that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Simmons understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Simmons meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Washington.

*Jerry G. Smith*

Mr. Smith, 38, has had ITDM since 2002. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Smith understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Smith meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from North Carolina.

*William J. Taylor*

Mr. Taylor, 60, has had ITDM since 2014. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Taylor understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Taylor meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Indiana.

*Roy E. Tompkins*

Mr. Tompkins, 74, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of

consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Tompkins understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Tompkins meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class B CDL from New York.

*Vasilios Tsimis*

Mr. Tsimis, 43, has had ITDM since 2014. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Tsimis understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Tsimis meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from New York.

*Craig J. Voudren*

Mr. Voudren, 56, has had ITDM since 1989. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Voudren understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Voudren meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from Virginia.

*Donald L. Yamauchi*

Mr. Yamauchi, 43, has had ITDM since 2015. His endocrinologist examined him in 2016 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Yamauchi understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Yamauchi meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2016 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

**III. Request for Comments**

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated in the date section of the notice.

FMCSA notes that section 4129 of the Safe, Accountable, Flexible and Efficient Transportation Equity Act: A Legacy for Users requires the Secretary to revise its diabetes exemption program established on September 3, 2003 (68 FR 52441).<sup>1</sup> The revision must provide for individual assessment of drivers with diabetes mellitus, and be consistent with the criteria described in section 4018 of the Transportation Equity Act for the 21st Century (49 U.S.C. 31305).

Section 4129 requires: (1) Elimination of the requirement for 3 years of experience operating CMVs while being treated with insulin; and (2) establishment of a specified minimum period of insulin use to demonstrate stable control of diabetes before being allowed to operate a CMV.

In response to section 4129, FMCSA made immediate revisions to the diabetes exemption program established by the September 3, 2003 notice. FMCSA discontinued use of the 3-year driving experience and fulfilled the requirements of section 4129 while continuing to ensure that operation of CMVs by drivers with ITDM will achieve the requisite level of safety

<sup>1</sup> Section 4129(a) refers to the 2003 notice as a "final rule." However, the 2003 notice did not issue a "final rule" but did establish the procedures and standards for issuing exemptions for drivers with ITDM.

required of all exemptions granted under 49 U.S.C. 31136(e).

Section 4129(d) also directed FMCSA to ensure that drivers of CMVs with ITDM are not held to a higher standard than other drivers, with the exception of limited operating, monitoring and medical requirements that are deemed medically necessary.

The FMCSA concluded that all of the operating, monitoring and medical requirements set out in the September 3, 2003 notice, except as modified, were in compliance with section 4129(d). Therefore, all of the requirements set out in the September 3, 2003 notice, except as modified by the notice in the **Federal Register** on November 8, 2005 (70 FR 67777), remain in effect.

**IV. Submitting Comments**

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov> and in the search box insert the docket number FMCSA-2016-0035 and click the search button. When the new screen appears, click on the blue "Comment Now!" button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period. FMCSA may issue a final determination at any time after the close of the comment period.

**V. Viewing Comments and Documents**

To view comments, as well as any documents mentioned in this preamble, go to <http://www.regulations.gov> and in the search box insert the docket number FMCSA-2016-0035 and click "Search." Next, click "Open Docket Folder" and you will find all documents and comments related to this notice.

Issued on: April 5, 2016.

**Larry W. Minor,**

*Associate Administrator for Policy.*

[FR Doc. 2016-08355 Filed 4-11-16; 8:45 am]

**BILLING CODE 4910-EX-P**

**DEPARTMENT OF TRANSPORTATION****Federal Motor Carrier Safety Administration**

[Docket No. FMCSA-2016-0024]

**Qualification of Drivers; Exemption Applications; Vision**

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Notice of applications for exemptions; request for comments.

**SUMMARY:** FMCSA announces receipt of applications from 25 individuals for exemption from the vision requirement in the Federal Motor Carrier Safety Regulations. They are unable to meet the vision requirement in one eye for various reasons. The exemptions will enable these individuals to operate commercial motor vehicles (CMVs) in interstate commerce without meeting the prescribed vision requirement in one eye. If granted, the exemptions would enable these individuals to qualify as drivers of commercial motor vehicles (CMVs) in interstate commerce.

**DATES:** Comments must be received on or before May 12, 2016. All comments will be investigated by FMCSA. The exemptions will be issued the day after the comment period closes.

**ADDRESSES:** You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA-2016-0024 using any of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.
- *Hand Delivery:* West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

- *Fax:* 1-202-493-2251.

*Instructions:* Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any

personal information provided. Please see the Privacy Act heading below for further information.

*Docket:* For access to the docket to read background documents or comments, go to <http://www.regulations.gov> at any time or Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

*Privacy Act:* In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to [www.regulations.gov](http://www.regulations.gov), as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at [www.dot.gov/privacy](http://www.dot.gov/privacy).

**FOR FURTHER INFORMATION CONTACT:** Christine A. Hydock, Chief, Medical Programs Division, (202) 366-4001, [fmcsamedical@dot.gov](mailto:fmcsamedical@dot.gov), FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64-113, Washington, DC 20590-0001. Office hours are 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds “such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.” FMCSA can renew exemptions at the end of each 2-year period. The 25 individuals listed in this notice have each requested such an exemption from the vision requirement in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting an exemption will achieve the required level of safety mandated by statute.

##### II. Qualifications of Applicants

###### *Stanley W. Ahne*

Mr. Ahne, 56, tore the iris in his right eye in childhood due to a traumatic incident. The visual acuity in his right eye is 20/400, and in his left eye, 20/20. Following an examination in 2015, his optometrist stated, “I believe that Mr. Ahne does have sufficient vision to drive a commercial vehical [sic] safely.” Mr. Ahne reported that he has driven straight trucks for 10 years, accumulating 100,000 miles and tractor-trailer combinations for 10 years, accumulating 1 million miles. He holds a Class A CDL from Oklahoma. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

###### *Marvin D. Bass*

Mr. Bass, 56, has been blind in his right eye since 2008 due to a traumatic incident. The visual acuity in his right eye is hand motion, and in his left eye, 20/20. Following an examination in 2015, his optometrist stated, “In my medical opinion, Mr. Bass has sufficient vision to perform the driving tasks required to operate a commercial vehicle.” Mr. Bass reported that he has driven straight trucks for 20 years, accumulating 700,000 miles. He holds an operator’s license from Kentucky. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

###### *Daniel L. Castonguay*

Mr. Castonguay, 54, has had macular degeneration in his left eye since 2012. The visual acuity in his right eye is 20/20, and in his left eye, 20/100. Following an examination in 2016, his optometrist stated, “It is my opinion that Daniel Castonguay has stable vision at this time and has sufficient vision to drive a commercial vehicle as he has done for the last 22 years.” Mr. Castonguay reported that he has driven straight trucks for 5 years, accumulating 250,000 miles and tractor-trailer combinations for 25 years, accumulating 1.5 million miles. He holds a Class A CDL from Maine. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

###### *William A. Crandall, Jr.*

Mr. Crandall, 31, has refractive amblyopia in his right eye since childhood. The visual acuity in his right eye is 20/60, and in his left eye, 20/15. Following an examination in 2016, his optometrist stated, “It is my opinion that Mr. Crandal [sic] has sufficient vision to perform the driving tasks

required to operate a commercial vehicle.” Mr. Crandall reported that he has driven straight trucks for 5 years, accumulating 100,000 miles. He holds an operator’s license from New York. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

###### *James T. Curtis*

Mr. Curtis, 55, has had ischemic optic neuropathy in his left eye since birth. The visual acuity in his right eye is 20/20, and in his left eye, light perception. Following an examination in 2016, his optometrist stated, “He has sufficient vision to perform the driving tasks required to operate a commercial vehicle.” Mr. Curtis reported that he has driven straight trucks for 17 years, accumulating 70,000 miles and tractor-trailer combinations for 17 years, accumulating 1,000 miles. He holds a Class A CDL from New Mexico. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

###### *Jacob M. Dellinger*

Mr. Dellinger, 60, had a branch retinal vein occlusion in his left eye in 2011. The visual acuity in his right eye is 20/20, and in his left eye, 20/200. Following an examination in 2015, his optometrist stated, “In my medical opinion, with his right eye correction to 20/20 and his full temporal peripheral fields, he has sufficient vision to perform the driving tasks required to operate a commercial vehicle.” Mr. Dellinger reported that he has driven straight trucks for 41 years, accumulating 410,000 miles and tractor-trailer combinations for 41 years, accumulating 123,000 miles. He holds an operator’s license from North Carolina. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

###### *Mark E. Dow*

Mr. Dow, 51, has had amblyopia in his right eye since birth. The visual acuity in his right eye is 20/70, and in his left eye, 20/20. Following an examination in 2016, his optometrist stated, “In my opinion Mr. Dow has sufficient vision to perform the driving tasks required to operate a commercial vehicle.” Mr. Dow reported that he has driven straight trucks for 30 years, accumulating 1.05 million miles and tractor-trailer combinations for 30 years, accumulating 150,000 miles. He holds a Class A CDL from Vermont. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Richard R. Filion*

Mr. Filion, 68, is blind in his left eye due to a traumatic incident in 2011. The visual acuity in his right eye is 20/20, and in his left eye, no light perception. Following an examination in 2015, his optometrist stated, "If there is an allowance or waiver given for monocular status then Mr. Filion would meet requirements for commercial driving." Mr. Filion reported that he has driven straight trucks for 25 years, accumulating 500,000 miles and tractor-trailer combinations for 8 years, accumulating 560,000 miles. He holds a Class A CDL from Vermont. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Louis J. Floquet Jr.*

Mr. Floquet, 31, has had Morning Glory Syndrome in his left eye since birth. The visual acuity in his right eye is 20/20, and in his left eye, light perception. Following an examination in 2015, his optometrist stated, "Based on these tests, Louis has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Floquet reported that he has driven straight trucks for 15 years, accumulating 150,000 miles. He holds an operator's license from California. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Joshua V. Harrison*

Mr. Harrison, 67, has had a corneal scar in his left eye since childhood. The visual acuity in his right eye is 20/25, and in his left eye, 20/80. Following an examination in 2015, his ophthalmologist stated, "Left eye poor vision is long-standing, right eye meets standards . . . for CDL." Mr. Harrison reported that he has driven straight trucks for 45 years, accumulating 450,000 miles. He holds a Class A CDL from New Jersey. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Jason G. Joyner*

Mr. Joyner, 38, has had strabismic amblyopia in his left eye since childhood. The visual acuity in his right eye is 20/20, and in his left eye, 20/100. Following an examination in 2016, his optometrist stated, "I believe pt [sic] has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. Joyner reported that he has driven straight trucks for 4 years, accumulating 150,000 miles. He holds a Class A CDL from Kansas. His driving record for the last 3 years shows no

crashes and no convictions for moving violations in a CMV.

*Thomas M. Kaley, Jr.*

Mr. Kaley, 43, is blind in his left eye due to a traumatic incident in childhood. The visual acuity in his right eye is 20/20, and in his left eye, no light perception. Following an examination in 2015, his optometrist stated, "I see no reason that he should be denied a license as I believe that he has sufficient vision to operate a commercial vehicle." Mr. Kaley reported that he has driven straight trucks for 25 years, accumulating 750,000 miles. He holds an operator's license from Pennsylvania. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*William J. Krynski*

Mr. Krynski, 56, has had optic atrophy in his left eye since 2012. The visual acuity in his right eye is 20/20, and in his left eye, hand motion. Following an examination in 2015, his optometrist stated, "I believe he can continue to safely operate his commercial motor vehicle for interstate driving without any restrictions." Mr. Krynski reported that he has driven tractor-trailer combinations for 35 years, accumulating 2.3 million miles. He holds a Class A CDL from Minnesota. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Bradley K. Linde*

Mr. Linde, 67, has had amblyopia in his left eye since childhood. The visual acuity in his right eye is 20/20, and in his left eye, 20/400. Following an examination in 2015, his optometrist stated, "In my professional opinion of his vision, Mr. Linde is qualified to perform all duties expected for operating a commercial vehicle." Mr. Linde reported that he has driven tractor-trailer combinations for 21 years, accumulating 10,500 miles. He holds a Class A CDL from Iowa. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Pedro Martinez*

Mr. Martinez, 55, has had a choroidal macular scar in his left eye since 1985. The visual acuity in his right eye is 20/20, and in his left eye, counting fingers. Following an examination in 2015, his optometrist stated, "In my medical opinion, he has sufficient vision centrally OD and Peripherally [sic] OU to operate a commercial vehical [sic]." Mr. Martinez reported that he has driven straight trucks for 10 years,

accumulating 5,200 miles. He holds an operator's license from New Mexico. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Ty N. Mason*

Mr. Mason, 51, has been blind in his left eye due to a retinal detachment in 2003. The visual acuity in his right eye is 20/20, and in his left eye, no light perception. Following an examination in 2015, his optometrist stated, "Patient has sufficient visual acuity and VF [sic] for CDL license." Mr. Mason reported that he has driven straight trucks for 2 years, accumulating 75,000 miles and tractor-trailer combinations for 16 years, accumulating 6.53 million miles. He holds a Class AM CDL from Pennsylvania. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Ralph A. Milliman*

Mr. Milliman, 63, has had an incomplete macular formation in his left eye since birth. The visual acuity in his right eye is 20/20, and in his left eye, 20/200. Following an examination in 2015, his optometrist stated, "It is my opinion that Mr. Milliman's exceptional vision in his right eye allows him to compensate for his lack of visual acuity in his left eye and leads me to believe he has sufficient vision to perform all commercial driving tasks." Mr. Milliman reported that he has driven straight trucks for 24 years, accumulating 1.92 million miles and tractor-trailer combinations for 33 years, accumulating 3.47 million miles. He holds an operator's license from Illinois. His driving record for the last 3 years shows no crashes and 1 conviction for a moving violation in a CMV; he operated in an improper traffic lane.

*Donald A. Orloski*

Mr. Orloski, 69, has had amblyopia in his left eye since birth. The visual acuity in his right eye is 20/20, and in his left eye, 20/150. Following an examination in 2015, his optometrist stated, "Mr. Orloski's visual condition is stable. I find no medical reason to prevent Donald Orloski from safely operating a commercial vehicle." Mr. Orloski reported that he has driven straight trucks for 37 years, accumulating 592,000 miles and tractor-trailer combinations for 37 years, accumulating 37,000 miles. He holds a Class A CDL from Pennsylvania. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.



*Alan R. Piroso*

Mr. Piroso, 60, has had amblyopia in his left eye since birth. The visual acuity in his right eye is 20/20, and in his left eye, 20/400. Following an examination in 2015, his ophthalmologist stated, "Alan Piroso has been driving for many years without a problem and I believe he should be able to renew his CDL license based on his eye examination." Mr. Piroso reported that he has driven straight trucks for 31 years, accumulating 930,000 miles and tractor-trailer combinations for 6 years, accumulating 30,000 miles. He holds a Class AMC CDL from New Hampshire. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Juan C. Ramirez*

Mr. Ramirez, 31, has had exotropia with amblyopia in his left eye since childhood. The visual acuity in his right eye is 20/30, and in his left eye, 20/100. Following an examination in 2015, his optometrist stated, "I believe Mr. Ramirez should be considered for [sic] federal vision exemption to operate a CMV in interstate commerce." Mr. Ramirez reported that he has driven straight trucks for 6 years, accumulating 600,000 miles and tractor-trailer combinations for 2 years, accumulating 120,000 miles. He holds a Class A CDL from Ohio. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Erik J. Rowland*

Mr. Rowland, 35, has had amblyopia in his right eye since birth. The visual acuity in his right eye is hand motion, and in his left eye, 20/15. Following an examination in 2015, his ophthalmologist stated, "It is my opinion that Mr. Rowland is able to operate a commercial vehicle, as his vision has remained stable, and he has operate [sic] a commercial vehicle for the past several years." Mr. Rowland reported that he has driven straight trucks for 17 years, accumulating 340,000 miles and tractor-trailer combinations for 2 years, accumulating 10,000 miles. He holds a Class A CDL from New York. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Colby T. Smith*

Mr. Smith, 36, has had amblyopia in his left eye since childhood. The visual acuity in his right eye is 20/20, and in his left eye, 20/400. Following an examination in 2015, his optometrist stated, "In my opinion, Colby has more

than adequate vision to perform all driving tasks required to operate a commercial vehicle." Mr. Smith reported that he has driven straight trucks for 10 years, accumulating 120,000 miles. He holds a Class D operator's license from Utah. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Carl J. Warnecke*

Mr. Warnecke, 55, has had amblyopia in his right eye since childhood. The visual acuity in his right eye is 20/200, and in his left eye, 20/20. Following an examination in 2015, his ophthalmologist stated, "I think that he does have sufficient vision to perform the driving tasks required to operate a commercial vehicle, according to their guidelines." Mr. Warnecke reported that he has driven straight trucks for 35 years, accumulating 210,000 miles and tractor-trailer combinations for 35 years, accumulating 35,000 miles. He holds a Class A CDL from Ohio. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Edwin E. West*

Mr. West, 55, has had a macular scar in his right eye due to a retinal hemorrhage in 2004. The visual acuity in his right eye is 20/70, and in his left eye, 20/20. Following an examination in 2015, his optometrist stated, "I certify that Ed West has sufficient vision to perform the driving tasks required to operate a commercial vehicle." Mr. West reported that he has driven straight trucks for 37 years, accumulating 185,000 miles and tractor-trailer combinations for 37 years, accumulating 185,000 miles. He holds a Class A CDL from Missouri. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

*Donald E. Wojtaszek*

Mr. Wojtaszek, 62, has had amblyopia in his left eye since childhood. The visual acuity in his right eye is 20/20, and in his left eye, 20/200. Following an examination in 2015, his optometrist stated, "I hereby certify that in my medical opinion, this individual has sufficient vision to perform driving tasks required to operate a commercial vehicle." Mr. Wojtaszek reported that he has driven straight trucks for 42 years, accumulating 84,000. He holds a Class C license from Pennsylvania. His driving record for the last 3 years shows no crashes and no convictions for moving violations in a CMV.

**III. Public Participation and Request for Comments**

FMCSA encourages you to participate by submitting comments and related materials.

*Submitting Comments*

If you submit a comment, please include the docket number for this notice, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov> and put the docket number FMCSA-2016-0024 in the "Keyword" box, and click "Search." When the new screen appears, click on "Comment Now!" button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

FMCSA will consider all comments and material received during the comment period. FMCSA may issue a final determination at any time after the close of the comment period.

*Viewing Comments and Documents*

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov> and insert the docket number FMCSA-2016-0024 in the "Keyword" box and click "Search." Next, click "Open Docket Folder" button and choose the document listed to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

Issued on: April 5, 2016.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2016-08354 Filed 4-11-16; 8:45 am]

BILLING CODE 4910-EX-P

## DEPARTMENT OF TRANSPORTATION

### Federal Transit Administration

#### **FY16 Competitive Funding Opportunity: Grants for Buses and Bus Facilities and Low or No Emission Grant Programs; 5339(b) Grants for Buses and Bus Facilities Program and 5339(c) Low or No Emission Program—Correction**

**AGENCY:** Federal Transit Administration (FTA), DOT.

**ACTION:** Notice; correction.

**SUMMARY:** On March 29, 2016, the Federal Transit Administration (FTA) published a Notice of Funding Opportunity (NOFO) in the **Federal Register** announcing the availability of approximately \$211 million for Grants for Buses and Bus Facilities and \$55 million for Low or No Emission Grants. The notice provided incomplete information regarding FTA's Buy America and Disadvantage Business Enterprise (DBE) requirements. Additionally, the NOFO was missing information in one place about how to submit applications through [www.grants.gov](http://www.grants.gov). This notice corrects the March 29 notice.

**FOR FURTHER INFORMATION CONTACT:** For the Bus Program, contact Sam Snead, FTA Office of Program Management, 202-366-1089, or [samuel.snead@dot.gov](mailto:samuel.snead@dot.gov). For the Low-No Program, contact Tara Clark, same office, 202-366-2623, or [tara.clark@dot.gov](mailto:tara.clark@dot.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **Need for Correction**

The FTA notice published in the **Federal Register** on March 29, 2016 (81 FR 17553), FR Doc. 2016-07027, contained errors. In subsection *F. Federal Award Administration, iii. Administrative and National Policy Requirements, iii. Buy America* and *iv. Disadvantaged Business Enterprise*, the notice provides incomplete information and refers to projects that involve passenger ferries, which are not eligible for funding under the Bus Program or Low-No Program. In section *G. Technical Assistance and Other Program Information*, the NOFO is missing the date by which applications must be submitted through [www.grants.gov](http://www.grants.gov).

Therefore, FR Doc. 2016-07027 is corrected as follows:

1. On page 17560, in the 2nd column, subsection *F. Federal Award Administration, iii. Administrative and National Policy Requirements, iii. Buy America* is corrected to read as shown below:

##### *iii. Buy America*

The FTA requires that all capital procurements meet FTA's Buy America requirements, which require that all iron, steel, or manufactured products be produced in the U.S. These requirements help create and protect manufacturing jobs in the U.S. The Bus Program and Low-No Program will have a significant economic impact toward meeting the objectives of the Buy America law. The FAST Act amended the Buy America requirements to provide for a phased increase in the domestic content for rolling stock. For FY16 and FY17, the cost of components and subcomponents produced in the United States must be more than 60 percent of the cost of all components. For FY18 and FY19, the cost of components and subcomponents produced in the United States must be more than 65 percent of the cost of all components. For FY20 and beyond, the cost of components and subcomponents produced in the United States must be more than 70 percent of the cost of all components. There is no change to the requirement that final assembly of rolling stock must occur in the United States. FTA will be issuing guidance on the implementation of the phased increase in domestic content in the near future. Any proposal that will require a waiver must identify the items for which a waiver will be sought in the application. Applicants should not proceed with the expectation that waivers will be granted, nor should applicants assume that selection of a project under the Low-No Program that includes a partnership with a manufacturer, vendor, consultant, or other third party constitutes a waiver of the Buy America requirements for rolling stock applicable at the time the project is undertaken.

2. On page 17560, in the 2nd column, subsection *F. Federal Award Administration, iii. Administrative and National Policy Requirements, iv. Disadvantaged Business Enterprise* is corrected to read as shown below:

##### *iv. Disadvantaged Business Enterprise*

The FTA requires that its recipients receiving planning, capital and/or operating assistance that will award prime contracts exceeding \$250,000 in FTA funds in a Federal fiscal year

comply with the Disadvantaged Business Enterprise (DBE) program regulations at 49 CFR part 26. Applicants should expect to include any funds awarded, excluding those to be used for vehicle procurements, in setting their overall DBE goal. Note, however, that projects including vehicle procurements remain subject to the DBE program regulations. The rule requires that, prior to bidding on any FTA-assisted vehicle procurement, entities that manufacture vehicles, perform post-production alterations or retrofitting must submit a DBE Program plan and goal methodology to FTA. The FTA will then issue a transit vehicle manufacturer (TVM) concurrence/certification letter. Grant recipients must verify each entity's compliance with these requirements before accepting its bid. A list of compliant, certified TVMs is posted on FTA's Web page at <https://www.fta.dot.gov/regulations-and-guidance/civil-rights-ada/eligible-tvms-list>. Please note, that this list is nonexclusive and recipients must contact FTA before accepting bids from entities not listed on this web-posting. Recipients may also establish project specific DBE goals for vehicle procurements. The FTA will provide additional guidance as grants are awarded. For more information on DBE requirements, please contact Jennifer Riess, Office of Civil Rights, 202-366-3084, email: [jennifer.riess@dot.gov](mailto:jennifer.riess@dot.gov).

3. On page 17560, in the 3rd column, section *G. Technical Assistance and Other Program Information* is corrected to insert a deadline for complete applications of 11:59 p.m. EDT on May 13, 2016.

Matthew J. Welbes,

Executive Director.

[FR Doc. 2016-08295 Filed 4-11-16; 8:45 am]

BILLING CODE 4910-57-P

## DEPARTMENT OF TRANSPORTATION

### Federal Transit Administration

[Safety Advisory 16-1]

#### **Stop Signal Overruns**

**AGENCY:** Federal Transit Administration (FTA), Department of Transportation (DOT).

**ACTION:** Notice of Safety Advisory.

**SUMMARY:** The Federal Transit Administration (FTA) issued Safety Advisory 16-1 regarding stop signal overruns on rail fixed guideway public transportation systems, and an accompanying letter to the State Safety Oversight (SSO) program managers and

the chief safety officers of rail transit systems, seeking data and information on stop signal overruns during 2015. Safety Advisory 16–1 and the accompanying letter are available in their entirety on the FTA public Web site at <http://www.fta.dot.gov/tso.html>.

**DATES:** The FTA is asking the directors of the SSO programs to submit the requested data and information by July 2016.

**FOR FURTHER INFORMATION CONTACT:** For program matters, Mr. Sam Shelton, Office of System Safety, telephone (202) 366–0815 or [Sam.Shelton@dot.gov](mailto:Sam.Shelton@dot.gov). For legal matters, Scott Biehl, Senior Counsel, telephone (202) 366–0826 or [Scott.Biehl@dot.gov](mailto:Scott.Biehl@dot.gov).

**SUPPLEMENTARY INFORMATION:** Across the rail transit industry, many if not most operators keep a database on the number of instances in which their passenger or maintenance vehicles over run a stop signal. In some instances, State Safety Oversight Agencies (SSOAs) have identified stop signal overruns as event data a Rail Fixed Guideway Public Transportation System (RFGPTS) must record and report to the SSOA, as part of the hazard management process in the System Safety Program Plans required by the FTA rules at 49 CFR part 659. The FTA considers stop signal overruns to be significant events, creating safety risks, with potentially catastrophic consequences. The FTA now seeks to better understand the prevalence of stop signal overruns throughout the industry. The FTA issued Safety Advisory 16–1, “Stop Signal Overruns,” which is eliciting data and information on stop signal overruns at RFGPTSs that occurred during calendar year 2015.

Specifically, FTA is requesting that each SSOA provide FTA with: (1) the total number of stop signal overruns that occurred during 2015 at each RFGPTS within the SSOA’s oversight; (2) each RFGPTS’s definition of stop signal overrun; (3) each RFGPTS’s definition of a stop signal/stop aspect (e.g., hand signal, stop sign, cab signal); (4) a description of the process each RFGPTS uses to internally detect stop signal overruns; and, (5) a description of the process each RFGPTS uses to report stop signal overruns to the SSOA. The FTA is requesting this data and information by July 2016. The FTA is making this request in accordance with its authority to request State Safety Oversight program information, codified at 49 CFR 659.39(d). Safety Advisory 16–1 and an accompanying letter addressed to the SSO program managers, and the chief safety officers of RFGPTSs, are available in their entirety

on the FTA public Web site at <http://fta.dot.gov/tso.html>.

Also, FTA is aware that a number of RFGPTSs keep data and information on stop signal overruns on their own volition, for the purpose of enhancing the safety of their operations, albeit they are not required to report that data and information to their SSOAs. The FTA seeks to develop as complete a database as practical, thus, FTA would appreciate these RFGPTSs submitting their data and information to their SSOAs, and in turn, the SSOAs providing that material to FTA. The cooperation of the entire rail transit industry would be very helpful in developing a better understanding of stop signal overruns, and in due course, a strategy for mitigating the safety risks created by stop signal overruns.

**Matthew J. Welbes,**

*Executive Director.*

[FR Doc. 2016–08353 Filed 4–11–16; 8:45 am]

**BILLING CODE P**

## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

[Docket No. NHTSA–2015–0029; Notice 2]

#### Mercedes-Benz USA LLC, Denial of Petition for Decision of Inconsequential Noncompliance

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

**ACTION:** Denial of petition.

**SUMMARY:** Mercedes-Benz USA LLC (MBUSA), on behalf of itself and its parent company Daimler AG (DAG), collectively referred to as “Mercedes” has determined that certain model year (MY) 2015 Mercedes-Benz C-Class (205 Platform) passenger cars do not fully comply with paragraph S10.18.4 of Federal Motor Vehicle Safety Standard (FMVSS) No. 108, *Lamps, Reflective Devices, and Associated Equipment*. Mercedes has filed a report dated February 9, 2015, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports*. Mercedes then petitioned NHTSA under 49 CFR part 556 requesting a decision that the subject noncompliance is inconsequential to motor vehicle safety.

**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. Mercedes’ Petition:* Pursuant to 49 U.S.C. 30118(d) and 30120(h) and the rule implementing those provisions at 49 CFR part 556, Mercedes 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 Mercedes’ petition was published, with a 30-day public comment period, on April 16, 2015 in the **Federal Register** (80 FR 20571). 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/>. Follow the online search instructions to locate docket number “NHTSA–2015–0029.”

*II. Vehicles Involved:* Affected are approximately 9,137 MY 2015 Mercedes-Benz C-Class (205 Platform) passenger cars manufactured from June 18, 2014 through September 5, 2014 at Mercedes’ Tuscaloosa, Alabama plant.

*III. Noncompliance:* Mercedes explains that the subject vehicles were manufactured with horizontal adjustment-visually aimed headlamps that have a lower beam and a horizontal adjustment mechanism that was not made inoperative at the factory. Specifically, the horizontal adjustment screw was not properly sealed off with non-removable sealing caps as necessary to fully meet the requirements of paragraph S10.18.4 of FMVSS No. 108.

*IV. Rule Text:* Paragraph S10.18.4 of FMVSS No. 108 requires in pertinent part:

S10.18.4 *Horizontal adjustment-visually aimed headlamp.* A visually/optically aimed headlamp that has a lower beam must not have a horizontal adjustment mechanism unless such mechanism meets the requirements of this standard for on vehicle aiming as specified in S10.18.8.

*V. Summary of MBUSA’s Analyses:* Mercedes stated its belief that the subject noncompliance is inconsequential to motor vehicle safety for the following reasons:

(A) Mercedes believes that new manufacturing methods, including the use of optical image processing to adjust the horizontal and the vertical illumination levels of headlamps in addition to the reduction in assembly tolerances for headlamp assemblies, has resulted in optimal headlamp adjustments on vehicles leaving their manufacturing plants. As a result, on-vehicle aiming devices are no longer common in the industry. Mercedes believes that this has led to the elimination of the need for horizontal headlamp adjustment on in-use

vehicles. Regarding the subject vehicles, Mercedes says there is generally no need for customers or repair shops to adjust the horizontal aim of headlamps.

(B) Mercedes states that they have only received five customer complaints in the United States, relating to alleged headlamp mis-aiming in the subject vehicles. None of the complaints relate to horizontal mis-aiming of the headlamps. In all instances customers brought their vehicles in for service by Mercedes repair shops, who know how to perform a headlamp readjustment properly, without using the horizontal adjustment screw.

(C) Mercedes states that they provide service instructions to U.S. repair shops that horizontal headlamp adjustment is not permitted and do not even mention that a horizontal headlamp adjustment screw exists. Similarly, the vehicle owner's manual does not include information about performing headlamp illumination adjustment. Thus, since the horizontal headlamp screw's existence is not mentioned in any sales or service instructions or manuals, use of the screw by the customer or repair facilities would be extremely unlikely.

(D) Mercedes also states that even if the screw were to be used, such adjustment would result in only minimal differences in illumination levels compared to the original levels because it provides only a minimal range of adjustment. Mercedes elaborated by stating that when the horizontal adjustment screw is turned to the far left or far right end-position, only a few measuring points are slightly above or below the FMVSS No. 108 required levels. Specifically, when the horizontal adjustment screw is turned to the maximum left end-position ( $-2.8^\circ$ ), only 4 out of 24 measuring points are above (3) or under (1) the required illumination levels. And when the horizontal adjustment screw is turned to the maximum right end-position ( $+3.2^\circ$ ), only 2 out of 24 measuring points are under the required illumination levels. Thus, the difference between these worst-case levels and the required minimum or maximum levels are very small. According to Mercedes' headlamp development engineers, a difference of 300 cd [candela] is unlikely to be noticed by a driver and would not affect oncoming traffic or visibility in any material way. In addition, the subject headlamps rely on a reflection-based system which Mercedes' believes leads to less glare than projection-based system.

Mercedes has additionally informed NHTSA that it has corrected the subject noncompliance on vehicles in subsequent production and that all

future vehicles will be in full compliance with FMVSS No. 108.

In summation, Mercedes believes that the described noncompliance of the subject 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 noncompliance as required by 49 U.S.C. 30120 should be granted.

#### NHTSA's Decision

*NHTSA'S Analysis:* Mercedes states that its service instructions to U.S. repair shops specify that horizontal headlamp adjustment is not permitted and that they do not mention the existence of a horizontal headlamp adjustment screw. Similarly, the vehicle owner's manual does not include information about performing headlamp adjustment. As a result, Mercedes concludes that use of the headlamps horizontal aiming screw by a customer or repair facilities would be extremely unlikely. This argument is not persuasive. As these vehicles get older and fall out of the warranty period, consumers will have more options for servicing than Mercedes dealerships. Further, many states also have vehicle inspection stations that periodically check and adjust headlamp aim and these entities may not be familiar with this headlamp design. Therefore, NHTSA contends that it is possible that entities not familiar with the subject vehicle's design may use the screw to adjust the horizontal aim.

NHTSA has granted prior inconsequentiality petitions with similar arguments; however, the prior petitions also demonstrated that the horizontal aiming mechanisms were difficult to access (see Bentley Motors, Inc., 76 FR 4744, and General Motors, 71 FR 34415). That is not the case for the Mercedes petition. Because no mention was made of the accessibility of the horizontal aiming mechanism, a NHTSA representative inspected a 2015 Mercedes C-Class and found that a non-sealed horizontal aiming mechanism would be easily accessible, and would likely be the first adjustment screw used to alter the headlamp adjustment by someone unfamiliar with this headlamp design. This is because the horizontal aiming mechanism screw is in plain view, whereas, the required vertical aiming mechanism is out of sight and only accessible through a non-descript hole in the upper radiator support using a long tool.

Mercedes also argued that even if the horizontal aim were adjusted, it would result in only minimal differences in

illumination levels that would be unlikely to be noticed by a driver or affect oncoming traffic in any material way. To substantiate its claim, Mercedes provided photometric test data at the extreme right and left adjustment of the horizontal aiming mechanism. (Mercedes did not provide any test data at intermediate locations of horizontal adjustment) When adjusted to the extreme left position, the initial measured intensity level was 1,035 candela at test point 1U-1.5L which is nearly 48% over the required maximum of 700 candela. Using a  $\frac{1}{4}$  degree reaim, an adjustment permitted by the standard for compliance test purposes, the measured intensity level dropped to 982 candela, but this is still 40% over the required maximum of 700 candela. A NHTSA sponsored study titled "Driver Perception of Just Noticeable Differences of Automotive Signal Lamp Intensities" (DOT HS 808 209, September 1994) demonstrated a change in luminous intensity of 25 percent or less is not noticeable by most drivers and is a reasonable criterion for determining the inconsequentiality of non-compliant signal lamps. The University of Michigan Transportation Research Institute (UMTRI) performed a follow-up study relative to lower beam headlamps titled "Just Noticeable Differences for Low-Beam Headlamp Intensities." (UMTRI-97-4, February 1997) In that report, UMTRI determined that the 25% limit for inconsequential noncompliance determinations was suitable for photometric test points that specified maximum intensities for glare protection. Based on these reports, exceeding the maximum intensity specification by 40% at test point 1U-1.5L, a glare protection point that limits the amount of light into the eyes of oncoming drivers, would be noticeable to other drivers. As explained in the agency's report, "Nighttime Glare and Driving Performance," (Report to Congress, February 2007) increased glare reduces seeing distance because it causes light to scatter in the eyes, which in turn reduces the contrast of roadway objects. Glare decreases visibility distance, increases reaction times to objects in the roadway, and increases recovery time after the eyes have been exposed to increased glare. All of these factors increase risks during nighttime driving.

*NHTSA'S Decision:* In consideration of the foregoing, NHTSA finds that Mercedes has not met its burden of persuasion that the subject FMVSS No. 108 noncompliance is inconsequential to motor vehicle safety. Accordingly, NHTSA hereby denies Mercedes'

petition and Mercedes is consequently obligated to provide notification of, and a free remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

**Authority:** 49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.95 and 501.8.

**Gregory K. Rea,**

*Associate Administrator for Enforcement.*

[FR Doc. 2016-08361 Filed 4-11-16; 8:45 am]

**BILLING CODE 4910-59-P**

## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

[Docket No. NHTSA-2015-0098; Notice 2]

#### Continental Tire the Americas, 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:** Continental Tire the Americas, LLC (CTA), has determined that certain Continental Tire brand T-type spare tires do not fully comply with paragraph S4.3(a) of Federal Motor Vehicle Safety Standard (FMVSS) No. 109, *New Pneumatic and Certain Specialty Tires*. CTA has filed a report dated August 25, 2015 and amended on October 1, 2015, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports*.

**ADDRESSES:** For further information on this decision contact Abraham Diaz, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), telephone (202) 366-5310, facsimile (202) 366-5930.

**SUPPLEMENTARY INFORMATION: I. Overview:** 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.

Notice of receipt of the petition was published with a 30-day public comment period, on October 29, 2015 in the **Federal Register** (80 FR 66613). 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-2015-0098.”

**II. Tires Involved:** Affected are approximately 3,627 Continental Tire brand CST 17 size T125/70R17 98M temporary spare tires sold to General Motors and also in small quantities in the replacement market. These tires were manufactured between March 18, 2012 and April 11, 2015.

**III. Noncompliance:** CTA explains that the noncompliance is that the tire size designation markings on the sidewalls of the subject tires do not contain the tire type code designator symbol from The Tire and Rim Association yearbook as required by paragraph S4.3(a) of FMVSS No. 109. Specifically, the subject tire size reads “125/70R17 98M” but should read “T125/70R17 98M” indicating the tire is a spare tire and for temporary use.

**IV. Rule Text:** Paragraph S4.3(a) of FMVSS No. 109 requires in pertinent part:

**S4.3 Labeling Requirements.** Except as provided in S4.3.1 and S4.3.2 of this standard, each tire, except for those certified to comply with S5.5 of § 571.139, shall have permanently molded into or onto both sidewalls, in letters and numerals not less than 0.078 inches high, the information shown in paragraphs S4.3(a) through (g) of this standard. On at least one sidewall, the information shall be positioned in an area between the maximum section width and bead of the tire, unless the maximum section width of the tire falls between the bead and one-fourth of the distance from the bead to the shoulder of the tire. . . .

(a) One size designation, except that equivalent inch and metric size designations may be used; . . .

**V. Summary of CTA’s Analyses:** CTA stated that the only missing marking on the sidewalls of the affected tires is the letter “T” as part of the size designation.

CTA also stated its belief that the omission of the tire size designation markings has no impact on the operational performance or durability of these tires or on the safety of vehicles on which these tires may be mounted and that the affected tires cannot be confused with normal P-metric or metric passenger tires for the following reasons:

1. Both sidewalls of the affected tires have permanently molded letters that are ½ inch tall with the words “TEMPORARY USE ONLY.”

2. Both sidewalls of the affected tires have permanently molded letters and numerals that are ½ inch tall with the words “INFLATE TO 420KPA (60PSI),” as required by section S4.3.5 of FMVSS No. 109.

3. The affected tires are intended as spare tires for the Chevy Impala, which is equipped with four ground tires of

size P235/[ ]55R17 98W. The ground tires are significantly different in width (approximately four inches wider) and in diameter (approximately three inches larger) than the subject spare tires.

4. The affected tires also have a starting tread depth of only 3/32 inch, whereas a typical P-metric or metric passenger tire has a much deeper tread depth of approximately 10/32 inch.

CTA also noted that they are not aware of any crashes, injuries, customer complaints or field reports associated with this noncompliance.

In addition, CTA informed NHTSA that it has corrected the mold at the manufacturing plant so that no additional tires will be manufactured with the subject noncompliance and that all remaining CTA inventory of the subject tires in their possession have been scrapped.

CTA also made reference to inconsequential noncompliance petitions that NHTSA previously granted concerning noncompliances that CTA believes are similar to the subject noncompliance.

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’s Decision

**NHTSA’s Analysis:** Labeling the tire size “125/70R17” instead of “T125/70R17,” violates paragraph S4.3(a) of FMVSS No. 109 because the tire is labeled with an incomplete tire size designation for temporary use tires, also referred to as spare tires.

NHTSA bases its decision on several points. First, CTS labeled the subject tires on both sidewalls with the words “TEMPORARY USE ONLY” and “INFLATE TO 420KPA (60PSI).” The maximum pressure labeled on the subject tires correlates with the pressure specified for all temporary use tires in the TRA’s tire publication. Together, these additional labels provide the user with the same information intended by the missing labels, and by spelling out the word TEMPORARY, provides that information in clear format. All other sidewall labels and safety information are correct.

Next, NHTSA agrees that the subject tires would not be confused with non-temporary tires used on vehicles for which the tires are intended because of the differences in geometry of the two types of tires. CTA indicated that the subject tires are approximately four

inches narrower and three inches smaller in diameter than the non-temporary tires that would be used on the vehicle for which the subject tires are also intended.

Finally, neither CTA nor NHTSA are aware of any crashes, injuries, customer complaints or field reports associated with the omitted labeling.

*NHTSA's Decision:* In consideration of the foregoing, NHTSA finds that CTA has met its burden of persuasion that the subject FMVSS No. 109 noncompliance in the affected tires is inconsequential to motor vehicle safety. Accordingly, CTA's petition is hereby granted and CTA is consequently exempted from the obligation of providing notification of, and a free 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 tires that CTA no longer controlled at the time it determined that the noncompliance existed. However, the granting of 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,**  
Director, Office of Vehicle Safety Compliance.  
[FR Doc. 2016-08362 Filed 4-11-16; 8:45 am]  
BILLING CODE 4910-59-P

## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

[Docket No. NHTSA-2013-0101; Notice 2]

#### Morgan 3 Wheeler Limited, Denial of Petition for Decision of Inconsequential Noncompliance

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

**ACTION:** Denial of petition.

**SUMMARY:** Morgan 3 Wheeler Limited (Morgan) has determined that certain model year (MY) 2012 and 2013 Morgan model M3W three-wheeled motorcycles do not comply with all of the requirements of Federal Motor Vehicle Safety Standard (FMVSS) No. 108, *Lamps, reflective devices, and associated equipment*. Specifically, the vehicles' headlamps are spaced further apart than permitted, and do not have the required "DOT" marking. Morgan has petitioned for an exemption from the recall notification and remedy requirements of 49 U.S.C. Chapter 301—"Motor Vehicle Safety" (Vehicle Safety Act) on the grounds that the noncompliances are inconsequential to motor vehicle safety. This notice announces and explains NHTSA's denial of Morgan's petition.

**FOR FURTHER INFORMATION CONTACT:** For further information on this decision contact Mike Cole, Office of Vehicle Safety Compliance, National Highway Traffic Safety Administration (NHTSA), telephone (202) 366-2334, facsimile (202) 366-5930.

#### SUPPLEMENTARY INFORMATION:

*I. Overview:* Pursuant to 49 U.S.C. 30118(d) and 30120(h) and the rule implementing those provisions at 49 CFR part 556, Morgan has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that the noncompliances are inconsequential to motor vehicle safety.

Notice of receipt of the petition was published, with a 30-day public comment period, on December 9, 2013 in the **Federal Register** (78 FR 73920). One comment was received from Peter C. Larsen of Liberty Motors, LLC. To view the petition and all supporting documents log onto the Federal Docket Management System Web site at: <http://www.regulations.gov/>. Follow the online search instructions to locate docket number "NHTSA-2013-0101."

*II. Vehicles involved:* Approximately 150 MY 2012 and 2013 Morgan model M3W three-wheeled motorcycles manufactured from August 1, 2012 to August 14, 2013 (subject vehicles) are affected.

*III. Noncompliances:* Morgan's petition concerns two requirements in FMVSS No. 108.<sup>1</sup> Both noncompliances involve the vehicles' headlights. Morgan states that the noncompliances are a result of a configuration error in its production line. The first noncompliance involves the spacing between the headlights. Paragraph S10.17.1.2.2 of FMVSS No. 108 specifies

that if motorcycle headlamps are horizontally disposed about the vertical centerline, the distance between the closest edges of their effective projected luminous lens areas must not be greater than 200 mm.<sup>2</sup> Morgan states in its petition that the subject motorcycles do not comply with this requirement because they are equipped with dual horizontally-mounted headlamps mounted 29 inches (737 mm) apart (lens edge to lens edge).

The second noncompliance concerns the lack of a required marking on the headlamps. Paragraph S6.5.1 of FMVSS No. 108 requires that the lens of each original equipment and replacement headlamp be marked with the symbol "DOT," either horizontally or vertically, to indicate certification under 49 U.S.C. 30115.<sup>3</sup> Morgan states in its petition that the subject vehicles do not include this marking.

*IV. Rule Text:* Paragraphs S7.9.6.2(b) and S10.17.1.2.2 of FMVSS No. 108 require in pertinent part:

Paragraph S7.9.6.2(b) (applies only to the subject vehicles manufactured before December 1, 2012).

If the system consists of two headlamps, each of which provides both an upper and lower beam, the headlamps shall be mounted either at the same height and symmetrically disposed about the vertical centerline or mounted on the vertical centerline. If the headlamps are horizontally disposed about the vertical centerline, the distance between the closest edges of their effective projected luminous lens areas shall not be greater than 200 mm (8 in.).

Paragraph S10.17.1.2.2 (applies only to the subject vehicles manufactured after December 1, 2012).

If the headlamps are horizontally disposed about the vertical centerline, the distance between the closest edges of their effective projected luminous lens areas must not be greater than 200 mm.

*V. Summary of Morgan's Petition and Comments:* Morgan petitions for relief from the recall provisions of the Vehicle Safety Act with respect to both of these noncompliances. Morgan makes several arguments to support its assertion that these noncompliances are inconsequential to motor vehicle safety.

With respect to the headlamp spacing noncompliance, Morgan contends that

<sup>2</sup> In a December 2007 final rule, NHTSA rewrote and reorganized FMVSS No. 108 to provide a more straightforward and logical presentation of the regulatory requirements. 72 FR 68234, Dec. 4, 2007. Those amendments became effective on December 1, 2012. 74 FR 58214, Nov. 12, 2009. The rewrite was not intended to make any substantive changes to the standard. The subject vehicle population includes vehicles manufactured both before and after this effective date. Prior to the effective date of the reorganized standard, the headlight spacing requirement was contained in S7.9.6.2(b).

<sup>3</sup> This provision was located at S7.2(a) in the pre-rewrite version of FMVSS No. 108.

the headlamps meet the “technical requirements” of FMVSS No. 108. Morgan also states that it does not believe that this noncompliance will increase the safety risk to vehicle occupants or approaching drivers. Morgan argues that the current horizontal spacing of 29 inches (737 mm) is in the best interests of road safety, because if the M3W complied with the existing motorcycle head lamp spacing requirement, other road users would not have an accurate indication of the width of an oncoming M3W. Morgan also argues that NHTSA has previously found a lighting separation noncompliance to be inconsequential.<sup>4</sup>

Morgan contends that the lens marking noncompliance is inconsequential to motor vehicle safety because the lamps meet the substantive requirements of FMVSS No. 108. Morgan also states that owners of Morgan vehicles almost exclusively go to Morgan dealers for replacement parts; the agency assumes that Morgan is implying that because the vehicle owner is likely to obtain a replacement part directly from a dealer, the owner can be confident that the headlamp complies with all applicable requirements, even though it lacks the proper “DOT” marking.

With respect to both noncompliances, Morgan asserts, based on its reading of previous inconsequentiality petition grants by NHTSA, that its noncompliances should be found to be inconsequential because the M3W is an exotic vehicle with no roof or doors, produced in very low numbers, driven a low number of miles, and likely to be operated on a limited basis, as opposed to an ordinary passenger automobile designed to be used as a family’s primary passenger vehicle. Morgan also states that there have been no reports of any safety issues or injuries related to the subject noncompliances. NHTSA received one comment on Morgan’s petition from Peter Larsen. Mr. Larsen makes several arguments in support of Morgan’s petition. First, Mr. Larsen asserts that a NHTSA-published guidebook on motorcycle requirements does not contain the 200 mm spacing requirement. Second, Mr. Larsen argues that when NHTSA promulgated this requirement it did not contemplate three-wheeled vehicles with the frontal aspect of a small automobile, for which headlights spaced more than 200 mm apart help to indicate the size and shape of the vehicle. Accordingly, Mr. Larsen contends that the 200 mm requirement, as applied to the subject vehicles, is not in the interest of safety. Third, Mr.

Larsen suggests that if the subject vehicles are remedied so that the dual headlights are replaced with a compliant center headlight, owners and dealers of the subject vehicles would likely remove the single center light and replace it with the dual, widely-spaced lights; and that a recall or design revision, Mr. Larsen asserts, would “criminalize” these actions. Finally, Mr. Larsen argues that many existing three-wheeled vehicles have similarly-spaced dual headlights, and it would be unjust to penalize Morgan’s similar design. Mr. Larsen requests that NHTSA “properly amend” FMVSS No. 108.

#### NHTSA’s Decision

*General Principles:* Federal motor vehicle safety standards are adopted only after the agency has determined, following notice and comment, that the performance requirements are objective, practicable, and meet the need for motor vehicle safety.<sup>5</sup> There is a general presumption that the failure of a motor vehicle or item of motor vehicle equipment to comply with an FMVSS increases the risk to motor vehicle safety beyond the level determined appropriate by NHTSA through the rulemaking process. To protect the public from such risks, manufacturers whose products fail to comply with an FMVSS are normally required to conduct a safety recall under which they must notify owners, purchasers, and dealers of the noncompliance and provide a remedy without charge.<sup>6</sup>

Congress has, however, recognized that under some limited circumstances a noncompliance may be “inconsequential” to motor vehicle safety. Neither NHTSA’s statute nor its regulations define “inconsequential.” NHTSA determines whether a particular noncompliance is inconsequential to motor vehicle safety based on the specific facts before the agency. The key issue in evaluating an inconsequentiality petition is whether the noncompliance is likely to increase the safety risk to individuals who experience the type of injurious event against which the standard was designed to protect.<sup>7</sup> The agency is not aware of any prior inconsequentiality petitions concerning either of the two requirements that are the subject of Morgan’s petition.

*NHTSA’s analysis:* The agency has determined that Morgan has not met its burden of persuasion that the

noncompliances are inconsequential to safety. The agency is therefore denying Morgan’s petition with respect to both noncompliances. The agency’s reasons for the denial are discussed below.

NHTSA is not persuaded by the arguments of Morgan or Mr. Larsen regarding the noncompliance with the headlamp spacing requirement in S10.17.1.2.2. Morgan’s assertion that the subject vehicles meet the “technical requirements” of FMVSS No. 108 is inaccurate because the distance requirement for headlamp configuration is clearly stated in the regulation as one of the requirements for compliance.<sup>8</sup> Morgan acknowledges in its Part 573 defect notification report that the headlamps on the subject vehicles do not comply with this requirement.

The agency is also not persuaded by Morgan and Mr. Larsen’s arguments that the noncompliance not only does not increase the safety risk, but is, in fact, safety-enhancing, because the wider-spaced headlamps convey a more accurate impression of the vehicle’s width to other motorists. An inconsequentiality petition is not the appropriate means to challenge the basis or appropriateness of a requirement specified in an FMVSS. The appropriate venue for such an argument is a petition for rulemaking to amend the current safety standard. Nevertheless, neither Morgan nor Mr. Larsen have offered persuasive evidence that either the standard or market conditions have changed to undermine the basis for the spacing limitation. The 200 mm maximum spacing requirement was added to the standard in 1998 in response to a petition for rulemaking. In the preamble to the final rule, NHTSA explained the rationale for the motorcycle headlight requirements: “[A]t the time that the motorcycle headlight requirements in Standard No. 108 were originally issued, the predominant concern was that the headlighting system clearly identify a motorcycle as such when the vehicle was being operated at night.”<sup>9</sup> The wider space between the headlamps on the subject vehicles could impair the ability of other motorists to identify the subject vehicle as a motorcycle. Such identification is important because motorists may be more alert or alter their driving in response to the presence of a motorcycle, since motorcycles are smaller, less enclosed, and less stable than passenger cars and other motor vehicles.<sup>10</sup> Even if the Morgan vehicle’s

<sup>5</sup> 49 U.S.C. 30111(a).

<sup>6</sup> 49 U.S.C. 30118–30120.

<sup>7</sup> General Motors Corp., Ruling on Petition for Determination of Inconsequential Noncompliance, 69 FR 19897, Apr. 14, 2004.

<sup>8</sup> S10.17.1.2.2.

<sup>9</sup> 63 FR 42582, 42582, Aug. 10, 1998.

<sup>10</sup> The noncompliance is also not de minimis. The headlamps on the subject vehicles are 29 inches

<sup>4</sup> See 64 FR 28864, May 27, 1999.

front end is wider than that of a typical two-wheeled motorcycle, the vehicle is still smaller, less enclosed, and less stable than passenger cars and other motor vehicles with which it shares the road. In addition, to further distinguish motorcycles from larger vehicles, NHTSA's regulations also allow modulation of motorcycle headlamp intensity to provide increased conspicuity.<sup>11</sup> If the subject Morgan motorcycles were equipped with modulators on its headlamps, the wide spacing of the headlamps could be perceived by other drivers as an emergency or police vehicle. If Morgan believed that lighting indicating the width of the vehicle would enhance the safety of the vehicle, Morgan could have accomplished this by adding supplemental lighting to the vehicle (e.g., parking lamps), keeping in mind that supplemental lighting may not impair the effectiveness of required lighting equipment.<sup>12</sup> We also note that the space between the headlamps is less than the wheel-to-wheel width of the vehicle, so the existing headlights do not accurately indicate the actual width of the vehicle.

Similarly, Mr. Larsen asserts that when NHTSA promulgated this headlamp spacing regulation it did not contemplate three-wheeled vehicles such as the subject vehicles, which, he states, display the frontal aspect of a small automobile. The initial Federal Motor Vehicle Safety Standards, published in 1967, defined a "motorcycle" as "a motor vehicle with motive power having a seat or saddle for the use of the rider and designed to travel on not more than three wheels in contact with the ground."<sup>13</sup> This definition, which is in effect today,<sup>14</sup> clearly includes the subject vehicles. While the M3W may be an unusual design, the vehicle configuration is unequivocally a motorcycle; as Mr. Larsen notes in his comment, "the Morgan 3 Wheeler follows the classic lighting scheme." Again, as we noted above, a petition for rulemaking, not an inconsequentiality petition, is the proper mechanism if Morgan or Mr. Larsen believes that the existing requirement is not appropriate for the subject vehicles.<sup>15</sup>

apart, while the maximum spacing permitted by the standard is 200 mm (7.9 in).

<sup>11</sup> S10.17.5.

<sup>12</sup> S6.2.1.

<sup>13</sup> 32 FR 2408, 2409, Feb. 3, 1967.

<sup>14</sup> 49 CFR 571.3.

<sup>15</sup> We note that subsequent to filing the present inconsequentiality petition, Morgan did file a petition for rulemaking on this issue. The agency is currently evaluating this petition.

Morgan also cites, in support of its petition, a prior agency decision granting a General Motors inconsequentiality petition.<sup>16</sup> That inconsequentiality petition concerned a noncompliance with a minimum required separation distance between a daytime running lamp (DRL) and a front turn signal. The purpose of that spacing requirement is to prevent masking of the turn signal lamp by the DRLs. The agency found that masking would not be an issue in that case because those vehicles incorporated front turn signals that were five times the required minimum area and four times brighter than the minimum required photometry. NHTSA went on to state that its research showed that high turn signal intensity was very important to prevent masking. Because the requirements at issue in the General Motors petition are intended to address a fundamentally different safety issue than the requirement from which Morgan is seeking a grant of inconsequential noncompliance, we do not find the General Motors petition to be relevant for our consideration of Morgan's petition; as discussed above, we believe that the greater than allowed distance between the headlamps might hinder other motorists from identifying the subject vehicles as motorcycles.

Mr. Larsen also states that he developed a motorcycle on which the subject vehicle is based, and states that the headlamp location was configured as described in NHTSA's published guidebook entitled "Requirements of Motorcycle Manufacturers." Mr. Larsen did not further identify this guide, but he appears to refer to the NHTSA guide entitled "Requirements for Motorcycle Manufacturers," published in February 2000.<sup>17</sup> This guide states that it "merely highlights the major requirements for manufacturers; each manufacturer should consult the specific statutes, regulations, and standards to determine its responsibilities."<sup>18</sup> The lighting standard (FMVSS No. 108) contains many motorcycle lighting requirements in addition to the limited subset of requirements that are summarized in Table IV of the NHTSA guide.

Mr. Larsen also suggests that if NHTSA were to deny Morgan's petition, it would "criminalize" owners and dealers of the subject vehicles (who, he asserts, will likely replace a single center light and replace it with dual, widely-spaced lights). This is incorrect.

<sup>16</sup> 64 FR 28864, May 27, 1999.

<sup>17</sup> Available at <http://www.nhtsa.gov/Laws+&+Regulations/Manufacturer+Info/Requirements+for+Motorcycle+Manufacturers>.

<sup>18</sup> *Id.* at pages 3 and 4.

Today's denial requires Morgan to notify owners of the subject vehicles of the noncompliance and to remedy the noncompliance if and when a vehicle owner presents a vehicle for repair. Neither NHTSA's denial nor the recall and remedy requirements impose any obligations on vehicle owners. Today's denial simply ensures that vehicle owners will be notified of the noncompliance and will have the opportunity to have their vehicle remedied, if the vehicle owner so chooses.<sup>19</sup>

Finally, the agency is not persuaded by Mr. Larsen's argument that it would be unjust to "suddenly penalize" and require Morgan to recall the subject vehicles because, he asserts, there are many three-wheeled vehicles with wide-spaced dual headlights similar to the subject vehicles. The spacing regulation at issue has been in effect since 1998. Moreover, it does not apply to all three-wheeled motorcycles currently on the road. It applies to vehicles manufactured or imported into the United States after the effective date of the 1998 final rule. Accordingly, it does not apply, for example, to vintage vehicles that were manufactured before the effective date of the final rule.

Regarding the "DOT" marking requirement, the agency is also not persuaded by Morgan's arguments. In the past, NHTSA has granted inconsequentiality petitions for lighting components that did not have certain required markings.<sup>20</sup> As we noted earlier, however, we are not aware of any prior inconsequentiality petitions concerning the "DOT" marking requirement at issue in Morgan's petition. We are not persuaded that the absence of the "DOT" mark is inconsequential to motor vehicle safety in this case. The "DOT" mark on a headlamp indicates that the lamp manufacturer has certified the lamp as conforming to all applicable requirements. Morgan has provided no information or data to demonstrate that the headlamps otherwise comply with the requirements of FMVSS No. 108. Morgan asserts that the lamps meet the

<sup>19</sup> NHTSA encourages vehicle owners to have recalled vehicles promptly remedied. We also note the statutory prohibition on making required safety elements inoperative. 49 U.S.C. 30122. This prohibition, however, applies only to manufacturers, distributors, dealers, and motor vehicle repair businesses. § 30122. It does not apply to individual vehicle owners. See Letter from NHTSA Chief Counsel Frank Seales, Jr. to Hamsar Diversco Inc., Jan. 22, 1999, available at <http://isearch.nhtsa.gov/search.htm>.

<sup>20</sup> See, e.g., 78 FR 22943, Apr. 17, 2013 (grant of inconsequentiality petition from Osram Sylvania Products, Inc. for noncompliance with the light source marking requirements of FMVSS No. 108 S7.7.).



“substantive” requirements of FMVSS No. 108, but has provided no information as to which requirements it considers “substantive” and which it does not. Morgan has submitted no compliance testing data or information showing that the lamps comply with all relevant requirements. Without such information and data, and without a “DOT” mark on the headlamp to imply that such information and data exist, the agency is unable to conclude that the lack of the “DOT” mark is the only noncompliant aspect of the headlamps.

In addition to the arguments addressed above, the agency is also not persuaded by two additional arguments Morgan makes for why it believes NHTSA should grant the petition with respect to both noncompliances. First, Morgan argues that its petition should be granted because the subject vehicle is an exotic vehicle produced in very low numbers and likely to be operated on a limited basis, as opposed to a passenger automobile designed to be used as a family’s primary passenger vehicle. In support of this argument, Morgan cites two previous agency decisions granting inconsequentiality petitions.<sup>21</sup> Both petitions concerned noncompliances with automatic restraint requirements in FMVSS No. 208. The agency’s decisions in those situations were based on the fact that it had already granted temporary exemption petitions from both manufacturers for the vehicle models at issue in those inconsequentiality petitions. The agency has not previously granted Morgan a temporary exemption for the noncompliances at issue in the present petition. Moreover, the “vehicle attributes” that Morgan implies those grants were based on—that the vehicles were exotic vehicles likely operated on a limited basis—were simply arguments made by the petitioners in those cases, and not, as Morgan’s petition implies, the basis for the agency’s decision. NHTSA expects manufacturers to fulfill their duties and responsibilities to provide vehicles that meet all safety standards regardless of production volume or estimated consumer use.

Second, Morgan states that there have been no reports of any safety issues or injuries related to the subject noncompliances. NHTSA does not consider the absence of complaints to show that the noncompliances are inconsequential to safety. The subject vehicle population is small, so the lack of reports or complaints may not be

surprising. Further, vehicle lighting functions as a signal to other motorists and pedestrians; if other motorists found the noncompliant lighting confusing, it is unlikely that those motorists would have been able to identify the subject vehicle and make a complaint to either NHTSA or Morgan. Most importantly, the absence of a complaint does not mean there have not been any safety issues, nor does it mean that there will not be safety issues in the future.

Finally, the agency observes that although Morgan’s Part 573 report and inconsequentiality petition only concern the headlamp spacing and headlamp marking noncompliances, the subject vehicles may also fail to comply with other applicable FMVSSs. For example, a motorcycle headlamp that incorporates a replaceable light source that does not comply with FMVSS No. 108, paragraph S11 (e.g., an H4 light source which is only permitted on motorcycle specific headlamps) is also required to have the headlamp lens permanently marked “motorcycle.” This marking may not have appeared on the headlamps of one of the subject vehicles the agency observed.

*Morgan’s proposed remedy:* Morgan proposes to add a single FMVSS No. 108 compliant headlamp on the M3W’s vertical centerline and have the original, noncompliant headlamps remain as separately switched auxiliary lamps. Paragraph S6.2.1 of FMVSS No. 108 requires that any additional lighting elements (i.e., lighting elements that are not required by the standard) installed on a vehicle must not impair the effectiveness of lighting equipment required by the standard. A motorcycle equipped with both a compliant single headlighting system and an auxiliary (supplemental) dual-headlamp system might be prohibited by the impairment provision. The proximity of the auxiliary lamps to the required front turn signal lamps might also raise impairment concerns. We strongly encourage Morgan to review the standard to ensure that its remedy does indeed comply with all applicable requirements.

*NHTSA’s Decision:* After carefully considering the arguments presented on this matter, NHTSA finds that the petitioner has not met its burden of persuasion in establishing that the described noncompliances in the subject vehicles are inconsequential to motor vehicle safety. Accordingly, Morgan’s petition is hereby denied, and Morgan must notify owners, purchasers and dealers pursuant to 49 U.S.C. 30118 and provide a free remedy in accordance with 49 U.S.C. 30120.

**Authority:** 49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.95 and 501.8.

**Gregory K. Rea,**

*Associate Administrator for Enforcement.*

[FR Doc. 2016–08360 Filed 4–11–16; 8:45 am]

**BILLING CODE 4910–59–P**

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## DEPARTMENT OF THE TREASURY

### Office of the Comptroller of the Currency

#### Agency Information Collection Activities: Information Collection Renewal; Comment Request; Notice Regarding Unauthorized Access to Customer Information

**AGENCY:** Office of the Comptroller of the Currency (OCC), Treasury.

**ACTION:** Notice and request for comment.

**SUMMARY:** The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA).

In accordance with the requirements of the PRA, the OCC 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 OCC is soliciting comment concerning its information collection titled, “Notice Regarding Unauthorized Access to Customer Information.”

**DATES:** Comments must be submitted on or before June 13, 2016.

**ADDRESSES:** Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0227, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to [regs.comments@occ.treas.gov](mailto:regs.comments@occ.treas.gov). You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597. Upon

<sup>21</sup> 60 FR 27593, May 24, 1995 (grant of inconsequentiality petition from Excalibur Automobile Corp.); 61 FR 9517, Mar. 8, 1996 (grant of inconsequentiality petition from Cantab Motors, Ltd.).

arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

**FOR FURTHER INFORMATION CONTACT:**

Shaquita Merritt, OCC Clearance Officer, (202) 649-5490 or, for persons who are deaf or hard of hearing, TTY, (202) 649-5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Suite 3E-218, Mail Stop 9W-11, Washington, DC 20219.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the 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) to include 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, the OCC is publishing notice of the proposed collection of information set forth in this document.

The OCC is proposing to extend, with revision, the approval of the following information collection:

*Title:* Notice Regarding Unauthorized Access to Customer Information.

*OMB Control No.:* 1557-0227.

*Description:* Section 501(b) of the Gramm-Leach-Bliley Act (15 U.S.C. 6801) requires the OCC to establish appropriate standards for national banks relating to administrative, technical, and physical safeguards: (1) To insure the security and confidentiality of customer records and information; (2) to protect against any anticipated threats or hazards to the security or integrity of such records; and (3) to protect against unauthorized access to, or use of, such records or information that could result in substantial harm or inconvenience to any customer.

The Interagency Guidelines Establishing Information Security

Standards, 12 CFR part 30, Appendix B and part 170, Appendix B (collectively, Security Guidelines), which implement section 501(b), require each entity supervised by the OCC (supervised institution) to consider and adopt a response program, as appropriate, that specifies actions to be taken when the supervised institution suspects or detects that unauthorized individuals have gained access to customer information.

The Interagency Guidance on Response Programs for Unauthorized Customer Information and Customer Notice (Breach Notice Guidance<sup>1</sup>), which interprets the Security Guidelines, states that, at a minimum, a supervised institution's response program should contain procedures for the following:

(1) Assessing the nature and scope of an incident, and identifying what customer information systems and types of customer information have been accessed or misused;

(2) Notifying its primary Federal regulator as soon as possible when the supervised institution becomes aware of an incident involving unauthorized access to, or use of, sensitive customer information;

(3) Consistent with the OCC's Suspicious Activity Report regulations, notifying appropriate law enforcement authorities and filing a timely SAR in situations in which a Federal criminal violation requires immediate attention, such as when a reportable violation is ongoing;

(4) Taking appropriate steps to contain and control the incident in an effort to prevent further unauthorized access to, or use of, customer information, for example, by monitoring, freezing, or closing affected accounts, while preserving records and other evidence; and

(5) Notifying customers as warranted. This collection of information covers the notice provisions in the Breach Notice Guidance.

*Type of Review:* Regular.

*Affected Public:* Businesses or other for-profit.

*Estimated Number of Respondents:* 20.

*Total Estimated Annual Burden:* 720 hours.

*Frequency of Response:* On occasion.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on:

(a) Whether the collection of information is necessary for the proper

performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the burden of the information collection;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection 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.

Dated: April 6, 2016.

**Mary Hoyle Gottlieb,**

*Regulatory Specialist, Legislative and Regulatory Activities Division.*

[FR Doc. 2016-08321 Filed 4-11-16; 8:45 am]

**BILLING CODE 4810-33-P**

**DEPARTMENT OF VETERANS AFFAIRS**

[OMB Control No. 2900-0219]

**Proposed Information Collection (Civilian Health And Medical Program of the Department of Veterans Affairs (CHAMPVA) Benefits—Application, Claim, Other Health Insurance & Potential Liability); Activity: Comment Request**

**AGENCY:** Veterans Health Administration, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** The Veterans Health Administration (VHA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to identify areas for improvement in clinical training programs.

**DATES:** Written comments and recommendations on the proposed collection of information should be received on or before June 13, 2016.

**ADDRESSES:** Submit written comments on the collection of information through the Federal Docket Management System

<sup>1</sup> 12 CFR part 30, Appendix B, Supplement A.

(FDMS) at [www.Regulations.gov](http://www.Regulations.gov); or to Brian McCarthy, Office of Regulatory and Administrative Affairs, Veterans Health Administration (10B4), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420 or email: [Brian.McCarthy4@va.gov](mailto:Brian.McCarthy4@va.gov). Please refer to “OMB Control No. 2900–0219” in any correspondence. During the comment period, comments may be viewed online through FDMS.

**FOR FURTHER INFORMATION CONTACT:**

Brian McCarthy at (202) 461–6345.

**SUPPLEMENTARY INFORMATION:** Under the PRA of 1995 (Pub. L. 104–13; 44 U.S.C. 3501–3521), Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VHA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VHA’s functions, including whether the information will have practical utility; (2) the accuracy of VHA’s estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

For RIN 2900–AP09, the Notice of Proposed Rule Making (NPRM) package was not submitted to OMB for review at the time of publication of the NPRM.

**Titles:**

1. VA Form 10–10d, Application for CHAMPVA Benefits
2. VA Form 10–7959a, CHAMPVA Claim Form
3. VA Form 10–7959c, CHAMPVA Other Health Insurance (OHI) Certification
4. VA Form 10–7959d, CHAMPVA Potential Liability Claim
5. VA Form 10–7959e, VA Claim for Miscellaneous Expenses
6. Payment (beneficially claims)
7. Review and Appeal Process

*OMB Control Number:* 2900–0219.

*Type of Review:* Revision of a currently approved collection.

**Abstracts**

1. VA Form 10–10d, Application for CHAMPVA Benefits, is used to determine eligibility of persons applying for healthcare benefits under the CHAMPVA program in accordance with 38 U.S.C. 501 and 1781.

2. VA Form 10–7959a, CHAMPVA Claim Form, is used to adjudicate claims for CHAMPVA benefits in accordance with 38 U.S.C. 501 and 1781, and 10 U.S.C. 1079 and 1086. This information is required for accurate adjudication and processing of beneficiary submitted claims. The claim form is also instrumental in the detection and prosecution of fraud. In addition, the claim form is the only mechanism to obtain, on an interim basis, other health insurance (OHI) information.

3. Except for Medicaid and health insurance policies that are purchased exclusively for the purpose of supplementing CHAMPVA benefits, CHAMPVA is always the secondary payer of healthcare benefits (38 U.S.C. 501 and 1781, and 10 U.S.C. 1086). VA Form 10–7959c, CHAMPVA—Other Health Insurance (OHI) Certification, is used to systematically obtain OHI information and to correctly coordinate benefits among all liable parties.

4. The Federal Medical Care Recovery Act (42 U.S.C. 2651–2653), mandates recovery of costs associated with healthcare services related to an injury/illness caused by a third party. VA Form 10–7959d, CHAMPVA Potential Liability Claim, provides basic information from which potential liability can be assessed. Additional authority includes 38 U.S.C. 501; 38 CFR 1.900 *et seq.*; 10 U.S.C. 1079 and 1086; 42 U.S.C. 2651–2653; and Executive Order 9397.

5. VA Form 10–7959e, VA Claim for Miscellaneous Expenses, information collection is needed to carry out the health care programs for certain children of Korea and/or Vietnam veterans authorized under 38 U.S.C., chapter 18, as amended by section 401, P.L. 106–419 and section 102, P.L. 108–183. VA’s medical regulations 38 CFR part 17 (17.900 through 17.905) establish regulations regarding provision of health care for certain children of Korea and Vietnam veterans and women Vietnam veterans’ children born with spina bifida and certain other covered birth defects. These regulations also specify the information to be included in requests for preauthorization and claims from approved health care providers.

6. Payment of Claims for Provision of Health Care for Certain Children of Korea and/or Vietnam Veterans (includes provider billing and VA Forms 10–7959e). This data collection is for the purpose of claiming payment/reimbursement of expenses related to spina bifida and certain covered birth defects. Beneficiaries utilize VA Form 10–7959e, VA Claim for Miscellaneous

Expenses. Providers utilize provider generated billing statements and standard billing forms such as: Uniform Billing-Forms UB–04, and CMS 1500, Medicare Health Insurance Claims Form. VA would be unable to determine the correct amount to reimburse providers for their services or beneficiaries for covered expenses without the requested information. The information is instrumental in the timely and accurate processing of provider and beneficiary claims for reimbursement. The frequency of submissions is not determined by VA, but will be determined by the provider or claimant and will be based on the volume of medical services and supplies provided to patients and claims for reimbursement are submitted individually or in batches.

**7. Review and Appeal Process**

Regarding Provision of Health Care or Payment Relating to Provision of Health Care for Certain Children of Korea and/or Vietnam Veterans. The provisions of 38 CFR 17.904 establish a review process regarding disagreements by an eligible veteran’s child or representative with a determination concerning provision of health care or a health care provider’s disagreement with a determination regarding payment. The person or entity requesting reconsideration of such determination is required to submit such a request to the Chief Business Office Purchased Care (CBOPC) (Attention: Chief, Customer Service), in writing within one year of the date of initial determination. The request must state why the decision is in error and include any new and relevant information not previously considered. After reviewing the matter, a Customer Service Advisor issues a written determination to the person or entity seeking reconsideration. If such person or entity remains dissatisfied with the determination, the person or entity is permitted to submit within 90 days of the date of the decision a written request for review by the Director, CBOPC.

*Affected Public:* Individuals or households.

**Estimated Annual Burden**

1. VA Form 10–10d—4,411 hours.
2. VA Form 10–7959a—37,336 hours.
3. VA Form 10–7959c—13,456 hours.
4. VA Form 10–7959d—467 hours.
5. VA Form 10–7959e—200 hours.
6. Payment (beneficially claims)—500 hours.
7. Review and Appeal Process—200 hours.

**Estimated Average Burden Per Respondent**

1. VA Form 10-10d—10 minutes.
2. VA Form 10-7959a—10 minutes.
3. VA Form 10-7959c—10 minutes.
4. VA Form 10-7959d—7 minutes.
5. VA Form 10-7959e—15 minutes.
6. Payment (beneficially claims)—10 minutes.

7. Review and Appeal Process—20 minutes.

*Frequency of Response:* Annually.

**Estimated Annual Responses**

1. VA Form 10-10d—26,468.
2. VA Form 10-7959a—224,018.
3. VA Form 10-7959c—80,733.
4. VA Form 10-7959d—4,000.
5. VA Form 10-7959e—800.

6. Payment (beneficially claims)—3,000.

7. Review and Appeal Process—600.

By direction of the Secretary.

**Kathleen M. Manwell,**

*Program Analyst, VA Privacy Service, Office of Privacy and Records Management, Department of Veterans Affairs.*

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Part II

## Environmental Protection Agency

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40 CFR Part 52

Air Plan Approval; Minnesota and Michigan; Revision to 2013 Taconite Federal Implementation Plan Establishing BART for Taconite Plants; Final Rule

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R05-OAR-2015-0196; FRL-9944-22-Region 5]

### Air Plan Approval; Minnesota and Michigan; Revision to 2013 Taconite Federal Implementation Plan Establishing BART for Taconite Plants

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is finalizing a revision to the Federal implementation plan (FIP) addressing the requirement for best available retrofit technology (BART) for taconite plants in Minnesota and Michigan. In response to petitions for reconsideration, we are revising the nitrogen oxides (NO<sub>x</sub>) limits for taconite furnaces at facilities owned and operated by Cliffs Natural Resources (Cliffs) and ArcelorMittal USA LLC (ArcelorMittal). Cliffs owns and operates Tilden Mining and United Taconite. Hibbing is owned by Cliffs, ArcelorMittal and U.S. Steel and operated by Cliffs. ArcelorMittal is owner and operator of Minorca Mine. We are also revising the sulfur dioxide (SO<sub>2</sub>) requirements at two of Cliffs' facilities. We are making these changes because new information has come to light that was not available when we originally promulgated the FIP on February 6, 2013.

**DATES:** This final rule is effective on May 12, 2016.

**ADDRESSES:** EPA has established a docket for this action under Docket ID No. EPA-R05-OAR-2015-0196. All documents in the docket are listed in the [www.regulations.gov](http://www.regulations.gov) index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either in [www.regulations.gov](http://www.regulations.gov) or at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Steven Rosenthal at (312) 886-6052 before visiting the Region 5 office.

**FOR FURTHER INFORMATION CONTACT:** Steven Rosenthal, Environmental

Engineer, Attainment Planning & Maintenance Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-6052, [rosenthal.steven@epa.gov](mailto:rosenthal.steven@epa.gov).

#### SUPPLEMENTARY INFORMATION:

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

- I. Definitions
- II. Background Information
- III. Comments and Responses
- IV. Revision to Equation for Normally Distributed but not Statistically Independent Data
- V. What action is EPA taking?
- VI. Statutory and Executive Order Reviews

#### I. Definitions

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

- The initials BACT mean or refer to Best Available Control Technology.
- The initials BART mean or refer to Best Available Retrofit Technology.
- The initials CAA mean or refer to the Clean Air Act.
- The initials CBI mean or refer to Confidential Business Information.
- The initials CEMS means or refers to continuous emission monitoring system.
- The initials CFD mean or refer to computational fluid dynamic.
- The words EPA, we, us, or our mean or refer to the United States Environmental Protection Agency.
- The initials FIP mean or refer to Federal Implementation Plan.
- The initials LNB mean or refer to low-NO<sub>x</sub> burners.
- The initials MACT mean or refer to Maximum Achievable Control Technology.
- The initials MCEA means or refers to the Minnesota Center for Environmental Advocacy.
- The initials MMBtu mean or refer to million British thermal units.
- The initials MW mean or refer to megawatts.
- The initials NAAQS mean or refer to National Ambient Air Quality Standards.
- The initials NESHAP mean or refer to National Emission Standards for Hazardous Air Pollutants.
- The initials NSPS mean or refer to Standards of Performance for New Stationary Sources.
- The initials NO<sub>x</sub> mean or refer to nitrogen oxides.
- The initials NPCA means or refers to the National Parks Conservation Association.
- The initials NTAA means or refers to the National Tribal Air Association.

- The initials PRB mean or refer to the Powder River Basin.
- The initials RHR mean or refer to the EPA's Regional Haze Rule.
- The initials RMB mean or refer to RMB Consulting and Research.
- The initials SCR mean or refer to Selective Catalytic Reduction.
- The initials SIP mean or refer to State Implementation Plan.
- The initials SO<sub>2</sub> mean or refer to sulfur dioxide.
- The initials UPL mean or refer to Upper Prediction Limit.

#### II. Background Information

##### A. Requirements of the Clean Air Act and EPA's Regional Haze Rule

In section 169A of the 1977 Amendments to the CAA, Congress created a program for protecting visibility in the nation's national parks and wilderness areas. This section of the CAA establishes as a national goal the “prevention of any future, and the remedying of any existing, impairment of visibility in mandatory Class I Federal areas<sup>1</sup> which impairment results from manmade air pollution.” Congress added section 169B to the CAA in 1990 to address regional haze issues. EPA promulgated a rule to address regional haze on July 1, 1999. 64 FR 35714 (July 1, 1999), codified at 40 CFR part 51, subpart P (herein after referred to as the “Regional Haze Rule”). The RHR revised the existing visibility regulations to add provisions addressing regional haze impairment and established a comprehensive visibility protection program for Class I areas. The requirements for regional haze, found at 40 CFR 51.308 and 51.309, are included in EPA's visibility protection regulations at 40 CFR 51.300-309.

##### B. Best Available Retrofit Technology (BART)

Section 169A of the CAA directs states, or EPA if developing a FIP, to

<sup>1</sup> Areas designated as mandatory Class I Federal areas consist of national parks exceeding 6000 acres, wilderness areas and national memorial parks exceeding 5000 acres, and all international parks that were in existence on August 7, 1977. 42 U.S.C. 7472(a). In accordance with section 169A of the CAA, EPA, in consultation with the Department of Interior, promulgated a list of 156 areas where visibility is identified as an important value. 44 FR 69122 (November 30, 1979). The extent of a mandatory Class I area includes subsequent changes in boundaries, such as park expansions. 42 U.S.C. 7472(a). Although states and tribes may designate as Class I additional areas which they consider to have visibility as an important value, the requirements of the visibility program set forth in section 169A of the CAA apply only to “mandatory Class I Federal areas.” Each mandatory Class I Federal area is the responsibility of a “Federal Land Manager.” 42 U.S.C. 7602(i). When we use the term “Class I area” in this action, we mean a “mandatory Class I Federal area.”

evaluate the use of retrofit controls at certain larger, often uncontrolled, older stationary sources in order to address visibility impacts from these sources. Specifically, section 169A(b)(2)(A) of the CAA requires EPA to develop a FIP that contains such measures as may be necessary to make reasonable progress toward the natural visibility goal, including a requirement that certain categories of existing major stationary sources<sup>2</sup> built between 1962 and 1977 procure, install, and operate the BART as determined by EPA. Under the RHR, states (or in the case of a FIP, EPA) are directed to conduct BART determinations for such “BART-eligible” sources that may reasonably be anticipated to cause or contribute to any visibility impairment in a Class I area.

On July 6, 2005, EPA published the *Guidelines for BART Determinations Under the Regional Haze Rule* at appendix Y to 40 CFR part 51 (hereinafter referred to as the “BART Guidelines”) to assist states and EPA in determining which sources should be subject to the BART requirements and in determining appropriate emission limits for each applicable source. 70 FR 39104.

The process of establishing BART emission limitations includes identifying those sources that meet the definition of “BART-eligible source” set forth in 40 CFR 51.301,<sup>3</sup> determining which of these sources “emits any air pollutant which may reasonably be anticipated to cause or contribute to any impairment of visibility in any such area” (a source which fits this description is “subject to BART”), and, for each source subject to BART, identifying the best available type and level of control for reducing emissions.

States, or EPA if developing a FIP, must address all visibility-impairing pollutants emitted by a source in the BART determination process. The most significant visibility impairing pollutants are SO<sub>2</sub>, NO<sub>x</sub>, and particulate matter.

A SIP or FIP addressing regional haze must include source-specific BART emission limits and compliance schedules for each source subject to BART. Once a state or EPA has made a BART determination, the BART controls must be installed and operated as

expeditiously as practicable, but no later than five years after the date of the final SIP or FIP. See CAA section 169A(g)(4) and 40 CFR 51.308(e)(1)(iv). In addition to what is required by the RHR, general SIP requirements mandate that the SIP or FIP include all regulatory requirements related to monitoring, recordkeeping, and reporting for the BART controls on the source. See CAA section 110(a).

### C. Regulatory and Legal History of the 2013 Taconite FIP

On February 6, 2013, EPA promulgated a FIP (78 FR 8706) that included BART limits for taconite furnaces subject to BART in Minnesota and Michigan. EPA took this action because Minnesota and Michigan had failed to meet a statutory deadline to submit their Regional Haze SIPs and subsequently failed to require BART at the taconite facilities. Cliffs, ArcelorMittal, and the State of Michigan petitioned the Eighth Circuit Court of Appeals for review of the FIP, and, on May 17, 2013, Cliffs and ArcelorMittal filed a joint motion for stay of the final rule, which was granted by the Eighth Circuit on June 14, 2013, and is still in effect.

EPA received petitions for reconsideration of the 2013 Taconite FIP from the National Mining Association on March 8, 2013, ArcelorMittal on March 22, 2013, the State of Michigan on April 1, 2013, Cliffs on April 3, 2013, Congressman Richard M. Nolan on April 8, 2013, the State of Minnesota on April 8, 2013, and United States Steel Corporation (U.S. Steel) on November 26, 2013.

In a related action, EPA published a final partial disapproval of the Michigan and Minnesota Regional Haze SIPs on September 30, 2013 (78 FR 59825), for failure to require BART for SO<sub>2</sub> and NO<sub>x</sub> emissions from taconite furnaces subject to BART. By petitions dated November 26, 2013, Cliffs and U.S. Steel petitioned EPA pursuant to section 307(d)(7)(B) of the CAA for reconsideration of EPA’s partial disapproval of the Michigan and Minnesota Regional Haze SIPs. Further, Cliffs, ArcelorMittal, Michigan, and U.S. Steel petitioned the Eight Circuit Court of Appeals for review of the final rule partially disapproving the Michigan and Minnesota Regional Haze SIPs.

EPA subsequently reached a settlement agreement with Cliffs, ArcelorMittal, and Michigan regarding issues raised by these parties in their petitions for review and reconsideration. Notice of the settlement was published in the **Federal Register** on January 30, 2015 (80 FR 5111), and

the settlement agreement was fully executed on April 9, 2015. Pursuant to the settlement agreement, EPA granted partial reconsideration of the 2013 Taconite FIP on July 2, 2015, based on new information raised in Cliffs’, ArcelorMittal’s, and Michigan’s petitions for reconsideration. EPA did not grant reconsideration of the 2013 SIP disapprovals because EPA continues to believe that BART for taconite plants involves significant reductions of NO<sub>x</sub> and SO<sub>2</sub> emissions that were not required in the Michigan and Minnesota SIPs.

### III. Comments on Proposed Action and Responses

On October 22, 2015, EPA published a **Federal Register** action entitled “Air Plan Approval; Minnesota and Michigan; Revision to Taconite Federal Implementation Plan; Proposed Rule” (80 FR 64160), which proposed to revise the 2013 Taconite FIP with respect to the BART emission limitations and compliance schedules for the following taconite plants: United Taconite, Hibbing Taconite, Tilden Mining, and ArcelorMittal Minorca Mine. Cliffs is the owner and operator of the United Taconite and Tilden Mining facilities and part owner and operator of Hibbing Taconite. ArcelorMittal is the owner and operator of the Minorca Mine facility and a part owner of the Hibbing Taconite facility.

EPA proposed to revise the NO<sub>x</sub> limits and compliance schedules for all four facilities and to revise the SO<sub>2</sub> requirements for Tilden Mining and United Taconite in response to new information that became available after the close of the public comment period of the 2013 FIP. Specifically, Cliffs and ArcelorMittal submitted information to EPA that suggested high-stoichiometric LNBs, which formed the basis of the original NO<sub>x</sub> limits, posed serious technical hurdles. Consequently, EPA proposed to determine that BART for taconite facilities was low-stoichiometric LNBs (for grate kilns) and a combination of water and steam injection and pre-combustion technologies (for straight-grate kilns) and proposed revised NO<sub>x</sub> limits based upon these technologies. Cliffs also submitted information showing that United Taconite could not burn very low-sulfur coal without challenges and that Tilden intended to burn mixed low-sulfur fuels instead of 100% natural gas. As a result, EPA proposed to revise the SO<sub>2</sub> limits for these facilities.

The public comment period on the proposal ended on December 23, 2015. EPA received comments from the National Park Service of the United

<sup>2</sup> The set of “major stationary sources” potentially subject to BART is listed in CAA section 169A(g)(7), and includes “taconite ore processing facilities.”

<sup>3</sup> BART-eligible sources are those sources that have the potential to emit 250 tons or more of a visibility-impairing air pollutant, were not in operation prior to August 7, 1962, but were in existence on August 7, 1977, and whose operations fall within one or more of 26 specifically listed source categories. 40 CFR 51.301.

States Department of Interior, the National Parks Conservation Association (NPCA), the Minnesota Center for Environmental Advocacy (MCEA), United States Steel Corporation, ArcelorMittal USA LLC, the Forest Service of the United States Department of Agriculture (USDA), Cliffs Natural Resources, and the Fond du Lac Band of Lake Superior Chippewa. The National Tribal Air Association (NTAA) requested an extension of the public comment period of 120 days. A 30-day extension of the public comment period was provided, but NTAA did not subsequently submit comments. EPA fully considered all of the comments and responds to each comment below. Based on our consideration of the comments, we are finalizing the NO<sub>x</sub> and SO<sub>2</sub> emission limits and compliance schedules as proposed, with two minor exceptions explained in Section V.

#### A. Comments by the Forest Service

*Comment:* The Forest Service disagreed with EPA's determination that LNBs should be eliminated as a potential BART option for straight-grate kilns. The Forest Service stated that LNBs are included in the permits for straight-grate furnaces for Essar Steel (Essar) in Minnesota and Magnetation in Indiana, which (unlike Essar) has commenced operation. The permit limits for each of the two LNB-equipped straight-grate kilns are 0.25 lbs NO<sub>x</sub>/MMBTU, which is lower than the limits proposed by EPA.

*Response:* EPA disagrees that the situations at Essar and Magnetation provide sufficient evidence that LNBs would be technically feasible at the Minorca Mine and Hibbing facilities. Essar and Magnetation were subject to the BACT requirement that applies to new and modified sources. Consequently, these facilities were able to integrate LNBs into the design and construction of their furnaces. In contrast, the furnaces at Minorca Mine and Hibbing were not designed to accommodate LNBs. As discussed in the proposal, EPA eliminated LNBs from consideration due to the technical challenges associated with a retrofit application on the unique straight-grate kilns at Minorca Mine and Hibbing. We also note that the Essar straight-grate furnace is still not operational, and Magnetation is not an iron ore processing facility and therefore is not classified as a taconite facility as defined by the taconite MACT (40 CFR part 63 subpart RRRRR). While Magnetation's permit limit is 0.25 lbs NO<sub>x</sub>/MMBTU, the results from an August-September 2015 test indicate

emissions ranging from 0.773 lbs NO<sub>x</sub>/MMBTU to 1.304 lbs NO<sub>x</sub>/MMBTU at that facility. Finally, we note that we are finalizing an initial emission limit of 1.2 lbs NO<sub>x</sub>/MMBTU (subject to upward revision only in unlikely scenarios) for the Minorca Mine and Hibbing furnaces, which is consistent with the limit in our 2013 FIP, but based on the installation of different technologies.

*Comment:* The Forest Service stated that EPA seems to assume that the only way to meet the existing 0.6 percent sulfur limit is to use western sub-bituminous coal, which will not work in the furnace due to its lower heating value. The Forest Service did a quick search of U.S. coal data (US DOE, NETL, Detailed Coal Specifications, Quality Guidelines for Energy System Studies, Final Report, DOE/NETL-401/012111, January 2012, page 31) and could find no eastern bituminous coal at 0.6 percent sulfur, but was able to find a low-volatile, eastern bituminous coal with very high heating value at 0.66 percent sulfur, which is far below the new limit proposed by EPA for United Taconite of 1.5 percent sulfur. The Forest Service stated that if an adjustment is warranted to the existing limit, it should be based on low-sulfur content eastern bituminous coal, such as the one at 0.66 percent sulfur.

*Response:* EPA disagrees with this comment. The primary SO<sub>2</sub> emission limit for BART at United Taconite is the 529 lbs SO<sub>2</sub>/hr aggregate limit on lines 1 and 2. This BART limit, which is based upon the use of low-sulfur fuels (a combination of natural gas and coal), will result in 1900 tons per year of SO<sub>2</sub> reductions. In contrast, the 1.5 percent sulfur limit is an operational limit that EPA imposed after Cliffs requested an adjustment to its baseline emission rate to be used in evaluating potential BART controls. Under the BART guidelines, the baseline emission rate ordinarily should represent a realistic depiction of anticipated annual emissions for the source based upon actual emissions from a baseline period. See 40 CFR part 51, appendix Y. However, when future operating parameters, such as type of fuel, will differ from past practice, and if this projection has a deciding effect in the BART determination, then the operating parameter must be made into an enforceable limitation. Id. EPA imposed the original 0.60 percent sulfur limit on the coal burned at United Taconite to comply with this provision. However, Cliffs indicated in its petition for reconsideration that 0.60 percent sulfur coal posed several issues for its furnaces. As a result, the EPA proposed to increase the operational limit to 1.5 percent sulfur, but this change will not

have an effect on emissions at United Taconite due to the 529 lbs SO<sub>2</sub>/hr limit. In essence, United Taconite will now be required to burn more natural gas and less coal (or all gas) to meet its BART limit than the facility would have under a 0.60 percent sulfur limit.

*Comment:* The Forest Service asked for an explanation as to why Minorca Mine and Tilden have the longest deadlines for compliance when they each have only one furnace at their facility.

*Response:* To establish an overall compliance schedule that is as expeditious as practicable, we grouped the furnaces according to whether they are straight-grate kilns or grate kilns, not according to which facility they belong. By grouping furnaces according to design and function rather than facility, Cliffs and ArcelorMittal will be able to take advantage of the experience gained from the first installation of NO<sub>x</sub> reduction technologies at a straight-grate kiln and grate kiln at the other furnaces. For example, Tilden will be able to take advantage of the experience of the earlier installation of a low-stoichiometric LNB on a grate kiln at United Taconite, while ArcelorMittal will be able to take advantage of the earlier installation of NO<sub>x</sub> reduction technologies on a straight-grate kiln at Hibbing. We believe that this staggered schedule is necessary because, although the selected NO<sub>x</sub> controls have been subject to extensive engineering studies, they have not been used on taconite furnaces in the United States to date. Such experience is necessary to ensure proper operation of these furnaces. Improper burner operation could adversely affect heat distribution throughout the furnace as well as pellet quality.

*Comment:* The Forest Service stated that it would like the opportunity to review and comment on the final emission limits.

*Response:* EPA has provided an extremely detailed and objective step-by-step procedure that will be used for determining the final emission limits. The notice of proposed rulemaking provided adequate information about the basis and timing of the final limits such that no further proposals will be necessary. The equations and an explicit explanation of how the final limits will be established are contained in the proposal, so the Forest Service could have raised any concerns during the public comment period. EPA is taking this approach in order to expedite the establishment of final enforceable limits for these facilities within the context of a process that provides reasonable time to design and install emission controls,



to obtain data needed for determining control effectiveness, and to minimize the time then needed to establish final enforceable limits. EPA has carefully considered the Forest Service's comments, but does not believe that a second comment period is necessary.

*Comment:* The Forest Service requested a description of how plant shutdowns will be handled.

*Response:* EPA is unsure what the commenter means by "plant shutdowns," but presumes that the Forest Service may be concerned that the emission limits could be relaxed during a shutdown. No special consideration has been given to plant shutdowns in this respect. The NO<sub>x</sub> limits are based on the production level and the quantity of fuel burned.

*Comment:* The Forest Service asked EPA to describe what will be done if adequate data are not collected within the timeframe envisioned in the schedule to establish a final emission limit.

*Response:* The eight-month testing period, during which controls will be in place and CEMS will be operational, should provide ample time for collecting data adequate to establish a final limit.

*Comment:* The Forest Service asked EPA to specify what design parameters will be monitored for the different control technologies.

*Response:* The design parameters will be established in the engineering reports that are required by the settlement agreement and this action. We anticipate that the percent stoichiometric primary combustion air and gas/coal ratio when co-firing will be important variables.

#### *B. Comments by the National Park Service*

*Comment:* The National Park Service, as well as NPCA and MCEA, commented on the technical feasibility of controlling NO<sub>x</sub> using SCR and encouraged EPA to further evaluate various configurations of SCR, including tail-end SCR with gas stream reheat (hereinafter referred to as "SCR with reheat").

*Response:* There are several air pollution control technology analyses involving the potential use of SCR and SCR with reheat on indurating furnace hood exhaust. In these analyses (Magnetation BACT, Essar BACT, and Tilden BART), SCR with reheat was rejected for not being cost-effective, while upstream SCR was rejected as technically infeasible due to the likelihood that the exhaust stream would foul the catalyst.

In a study conducted by Hatch for U.S. Steel, SCR with reheat was considered as a potential control option, but further discussion with potential vendors resulted in the determination that SCR with reheat is not a technically feasible control option for taconite indurating furnaces. One potential vendor, Mitsubishi Power Systems, cited temperature and layout as factors rendering SCR with reheat less than optimal for NO<sub>x</sub> control from U.S. Steel's Minntac taconite indurating furnaces. LKAB, a taconite facility in Sweden, has an SCR with reheat on its KK4 taconite pelletizing line. Alstom, the SCR vendor for LKAB, declined twice to bid on an SCR with reheat at Minntac, citing technical difficulties with the SCR with reheat at LKAB. These difficulties included operating within the narrow temperature range required by SCR with reheat. Further, LKAB is looking into process optimization and better burners to reduce NO<sub>x</sub> as opposed to installing another SCR with reheat in the future. It is important to note that SCR with reheat, even if it were technically feasible, would result in additional energy and environmental costs in the form of increased usage of natural gas and greenhouse gas emissions, respectively. While increased energy and environmental penalties are not preclusive, they further weigh against any additional analysis of SCR with reheat as a viable option for indurating furnaces at this time. We expect Minnesota and Michigan to reevaluate SCR with reheat as a potential option for making reasonable progress in future planning periods, but reject the technology as BART for the Minnesota and Michigan taconite facilities at this time.

*Comment:* The National Park Service concurred with the maximum 3.0 lbs NO<sub>x</sub>/MMBTU limit when burning natural gas only at grate kilns. However, the National Park Service did not believe that allowing NO<sub>x</sub> emissions to increase by 87 percent above expected levels when burning a gas/coal mix at grate kilns is justified.

*Response:* Low-stoichiometric LNBs, as designed by FCT Combustion (FCT), are designed to reduce NO<sub>x</sub> while maintaining pellet quality and production and optimizing fuel efficiency. As a result, this LNB was selected to establish BART limits for Cliffs' grate-kiln furnaces. FCT's computational fluid dynamic (CFD) modeling for co-firing at 30 percent gas and 70 percent coal indicated a reduction from a base case of 1.6–5.4 lbs NO<sub>x</sub>/MMBTU with a typical baseline value of 2.5 lbs NO<sub>x</sub>/MMBTU, to 2.04

lbs NO<sub>x</sub>/MMBTU. Therefore, an increase from 2.04 to 2.5 lbs NO<sub>x</sub>/MMBTU is a 23 percent increase above expected levels, which is more meaningful than the 67 percent increase (not 87 percent) above the low end of the range of the final emission limits. It should be noted that, in addition to the uncertainty resulting from the lack of experience in the use of low-stoichiometric LNBs, there is additional uncertainty because the CFD modeling was only performed for co-firing at 30 percent gas and 70 percent coal. Furthermore, a rigorous demonstration would have to be made that 1.5 lbs NO<sub>x</sub>/MMBTU cannot be met before the limit is adjusted and an alternative final limit is set.

*Comment:* The National Park Service was concerned that, although the proposed FIP requires the NO<sub>x</sub> reduction technologies for the straight-grate furnaces at Minorca Mine and Hibbing be designed to meet a limit of 1.2 lbs NO<sub>x</sub>/MMBTU, EPA is proposing to increase the final limit up to 1.8 lbs NO<sub>x</sub>/MMBTU if a rigorous demonstration is made that the 1.2 lbs NO<sub>x</sub>/MMBTU limit cannot be met. This represents a 50 percent increase above the expected emission rate and no justification is provided for such a large "safety margin."

*Response:* As discussed in the proposed rulemaking, EPA is confident that Minorca Mine and Hibbing can meet a limit of 1.2 lbs NO<sub>x</sub>/MMBTU based upon the engineering report prepared for ArcelorMittal that assesses the use of water and steam injection and pre-combustion technologies. However, because this suite of technologies has not previously been used on straight-grate kilns, some uncertainty remains regarding the potential effect on pellet quality. As a result, EPA has provided a procedure by which the final limits for Minorca Mine and Hibbing could be revised upwards to as much as 1.8 lbs NO<sub>x</sub>/MMBTU. It is important to note, however, that EPA has included rigorous requirements that must be met before any relaxing of the initial 1.2 lbs NO<sub>x</sub>/MMBTU limit would be allowed.

*Comment:* The National Park Service stated that EPA has the authority to limit the sulfur content of the fuels already fired at United Taconite. The National Park Service understood that United Taconite has identified problems with the characteristics of the 0.6 percent sulfur coal originally proposed by EPA and the compatibility of that coal with the United Taconite furnace. The National Park Service cited EPA's statement that it "is also establishing a limitation on the coal to be used by requiring the coal have a sulfur content

no greater than 1.5 percent sulfur by weight based on a monthly block average.” However, the National Park Service stated that it is aware of eastern bituminous coals that have much lower sulfur contents and requested that EPA evaluate the potential for combustion of such coals at United Taconite.

*Response:* EPA disagrees with this comment. The primary SO<sub>2</sub> emission limit for BART at United Taconite is the 529 lbs SO<sub>2</sub>/hr aggregate limit on lines 1 and 2. This BART limit, which is based upon the use of low-sulfur fuels (a combination of natural gas and coal), will result in 1900 tons per year of SO<sub>2</sub> reductions. In contrast, the 1.5 percent sulfur limit is an operational limit that EPA imposed after Cliffs requested an adjustment to its baseline emission rate to be used in evaluating potential BART controls. Under the BART guidelines, the baseline emission rate ordinarily should represent a realistic depiction of anticipated annual emissions for the source based upon actual emissions from a baseline period. See 40 CFR part 51, appendix Y. However, when future operating parameters, such as type of fuel, will differ from past practice, and if this projection has a deciding effect in the BART determination, then the operating parameter must be made into an enforceable limitation. *Id.* EPA imposed the original 0.60 percent sulfur limit on the coal burned at United Taconite to comply with this provision. However, Cliffs indicated in its petition for reconsideration that 0.60 percent sulfur coal posed several issues for its furnaces. As a result, the EPA proposed to increase the operational limit to 1.5 percent sulfur, but this change will not have an effect on emissions at United Taconite due to the 529 lbs SO<sub>2</sub>/hr limit. In essence, United Taconite will now be required to burn more natural gas and less coal (or all gas) to meet its BART limit than the facility would have under a 0.60 percent sulfur limit.

*Comment:* The National Park Service stated that EPA was apparently proposing to use hourly emission rates measured by a CEMS to derive the UPL. The National Park Service questioned the appropriateness of basing the UPL on hourly values if EPA is setting a 30-day (or 720-hour) rolling average limit. The National Park Service was concerned that the use of hourly values would introduce excess variability into the calculation and could lead to a higher UPL.

*Response:* When the UPL equation for normally distributed and statistically independent data is used, the average, standard deviation (s), and number of values (n) are based on the hourly data. The term number of values used to

calculate the test average) is based on the compliance period, *i.e.*, 720 for a 720-hour average and not 1. This results in a lower and more stringent UPL than if 1. However, when setting a 720-hour average emission limit using the nonparametric equation, the data set used would be the 720-hour averages rather than the raw hourly data.

### C. Comments by the National Parks Conservation Association (NPCA)

#### 1. NPCA Incorporated the Comments Submitted by the National Park Service

*Comment:* NPCA restated the National Park Service comments as follows:

- SCR remains a feasible technical option for limiting NO<sub>x</sub> from taconite facilities. While two SCR vendors declined to bid on the NO<sub>x</sub> reduction testing at Minntac, this is an insufficient basis to reject SCR across the taconite industry. EPA should revisit this decision and evaluate various configurations of SCR that would serve to further reduce NO<sub>x</sub> emissions beyond the limits in the proposed settlement.
- EPA’s proposed NO<sub>x</sub> limits for the gas/coal scenario at United Taconite and Tilden are improper because they are up to 87 percent higher than the limits in the 2013 FIP.
- EPA’s proposed NO<sub>x</sub> limits for Hibbing and Minorca Mine are improper because they are up to 50 percent higher than the limits in the 2013 FIP.
- EPA should require the use of an alternative low-sulfur coal at United Taconite.

*Response:* EPA has responded in detail to these comments in responses to the comments by the National Park Service (see above).

*Comment:* NPCA stated that the proposal specifies that increased limits are permissible where the industry makes a rigorous demonstration that lower limits cannot be met. NPCA requested that any such demonstration be made available to the public for review and comment.

*Response:* EPA has provided an extremely detailed and objective step-by-step procedure for determining the final emission limits. The notice of proposed rulemaking provided adequate information about the basis and timing of the final limits such that no further proposals will be necessary. EPA is taking this approach in order to expedite the establishment of final enforceable limits for these facilities within the context of a process that provides reasonable time to design and install emission controls, to obtain data needed for determining control

effectiveness, and to minimize the time then needed to establish final enforceable limits. The proposal encouraged commenters to comment on any issues that might be anticipated to arise at any point in the process described in the proposal, and NPCA has not identified any such issues.

#### 2. NPCA Incorporated Its March 2, 2015 Comments Regarding the Settlement Agreement

*Comment:* NPCA stated that the changes in emission limits between the 2013 FIP and the settlement agreement appear to significantly weaken the terms of the 2013 FIP because the emission limits are far less stringent. Although NPCA did not have the necessary level of detailed information to perform a precise comparison, NPCA’s rough calculations indicated that the limitations in attachment A of the settlement agreement would allow for pollution at or above the actual baseline emissions from the taconite facilities, that is, they represent no reduction (or at a minimum, no significant reduction) in pollution.

*Response:* As discussed in the five-step BART determinations in the proposal, there are significant emission reductions from the revised limits. There will be an estimated total of 3,000 tons per year of NO<sub>x</sub> reductions from Tilden and United Taconite, a total of 7,400 tons per year of NO<sub>x</sub> reductions from Minorca Mine and Hibbing, 1,900 tons per year of SO<sub>2</sub> reductions from United Taconite, and 300 tons of SO<sub>2</sub> reductions from Tilden. The only NO<sub>x</sub> emission limits that are definitely less stringent than those in the 2013 FIP are the NO<sub>x</sub> emission limits for Tilden and United Taconite when burning solely natural gas. The final NO<sub>x</sub> emission limits for Hibbing and Minorca Mine, as well as Tilden and United Taconite when co-firing coal and natural gas, are expected to be the same as, or close to, the 2013 FIP limits. There may also be an increase in SO<sub>2</sub> emissions from Tilden, but this should be a fairly small increase as Tilden will be solely burning natural gas and very low (0.6 percent) sulfur coal.

*Comment:* NPCA argued that the timeframes for compliance are significantly longer than in the 2013 FIP.

*Response:* The compliance schedule is generally similar to the FIP except that implementation has been delayed because of the court-imposed stay. The main differences between the two schedules are that Tilden must install controls within 50 months (compared with 26 months in the 2013 FIP) and Minorca Mine must install controls

within 44 months (compared with 26 months in the 2013 FIP). The staggered compliance schedule, which includes additional time for Tilden and ArcelorMittal, is necessary because the NO<sub>x</sub> controls selected as BART have not been used on taconite furnaces in the United States. Such experience is necessary to ensure proper operation of these furnaces. The planned controls could adversely affect heat distribution throughout the furnace as well as pellet quality.

*Comment:* NPCA stated that, in proposing the settlement, EPA offered no support to suggest why such a significant weakening of much needed and statutorily required limits was appropriate. NPCA was thus at a loss to comment on the rationale behind the changes.

*Response:* As discussed in a prior response, EPA does not agree that there has been a significant weakening of the requirements for taconite facilities. EPA's basis for all changes was contained in the proposed FIP revision and its associated docket.

*Comment:* NPCA stated that EPA must provide documentation of the reasons for the proposed changes in the form of publicly available information. EPA cannot rely strictly on confidential information, which does not allow the public to review and consider the changes proposed.

*Response:* Publicly available information in support of the FIP is contained in the docket.

*Comment:* NPCA stated that the settlement referenced "equitable treatment of facilities not included in this settlement." This would appear to refer to the taconite facilities covered by the 2013 FIP but not included in the settlement. To the extent that this statement refers to the potential weakening of limits imposed at other facilities in the taconite FIP, the increase in pollution that appears in the settlement is all the more concerning.

*Response:* EPA has not proposed to change the emission limits for other facilities covered by the 2013 FIP at this time.

*Comment:* NPCA stated that the timeframe for compliance detailed in the settlement agreement was inappropriate. The CAA requires that controls required under BART be implemented within five years of the final rule. In this case, the rule was finalized in January 2013, so compliance with emission limits must be by January 2018.

*Response:* We disagree with this comment. Section 169A(g)(4) of the CAA requires compliance with BART emission limits no later than five years

after "the date of promulgation of a . . . [FIP] revision." In this final rule, we are promulgating a revision to the 2013 FIP that includes new BART determinations based on new technologies. These BART determinations fully supersede the determinations that were made in the 2013 FIP. The taconite facilities must comply with the new BART emission limits in a staggered schedule that we have determined is as expeditious as practicable. Full compliance at all facilities will be achieved no later than five years from the date of the promulgation of this FIP revision.

#### *D. Comments by Cliffs Natural Resources*

*Comment:* Cliffs supported the proposed FIP, including the initial limits, the staggered compliance schedule, and the formula for setting final limits if the initial limits cannot be achieved without adverse impacts on pellet quality. However, Cliffs objected to EPA's statement in the proposed FIP preamble that "there are no significant costs or environmental impacts" associated with the selected BART technologies. Cliffs will be required to expend millions of dollars to design and implement changes to its furnaces. There are also costs associated with lost production during downtime and shakedown, as well as the potential for additional fuel consumption when the BART technologies are operational.

*Response:* EPA acknowledges that there will be costs associated with the BART control technologies employed by Cliffs. EPA's full statement in the preamble was that "there are no significant costs or environmental impacts associated with this technology that would necessitate its elimination from consideration as BART." EPA continues to believe that the costs, energy, and non-air quality impacts associated with the selected BART controls are reasonable.

*Comment:* Cliffs stated that EPA's proposal included a new requirement to report CEMS and pellet quality data at the end of a period that did not fall within the preceding calendar quarter within 7 days of the close of the period. Reporting this information within 7 days is impracticable, as it does not provide the facility sufficient time to complete the appropriate laboratory analysis and quality assurance expected for the data. Cliffs acknowledged EPA's need to include a provision to address the timely reporting of data, but requested that the reporting obligation be changed from 7 days to 30 days to allow for quality assurance checks.

*Response:* Using United Taconite Line 2 as an example, the settlement

agreement states that, 44 months from the effective date of the rule, Cliffs must provide results from pellet quality analyses no later than 30 days from the end of each calendar quarter until 52 months from the effective date of the rule. No later than 55 months after the effective date of the rule, EPA will take final agency action by publishing the NO<sub>x</sub> limits in the **Federal Register**. Assuming that the effective date of the rule is June 15, 2016, then 52 months from the effective date is October 15, 2020, and 55 months is January 15, 2021. The end of the quarter would be December 31, 2020, so under the settlement language, the pellet quality data from October 1 through October 15, 2020, would not be due until January 30, 2021, which is too late to be considered in establishing the final emission limit. According to the language in the proposal, the pellet quality analyses would need to be submitted to EPA by October 22, 2020. Accepting Cliffs' suggested revision from 7 to 30 days would require the pellet quality analysis to be submitted to EPA by November 14, 2020. EPA accepts Cliffs' basis for increasing the reporting requirement from 7 to 30 days and will make this revision in the final FIP because it will not significantly interfere with expeditiously setting the final limits.

*Comment:* Cliffs stated that United Taconite's pellet quality reporting obligations in the proposed FIP mistakenly refer to "Tilden's ISO 9001 quality management system" but should refer to "United Taconite's ISO 9001 quality management system."

*Response:* EPA acknowledges the error and has made the correction in the final FIP.

#### *E. Comments by the Fond du Lac Band of Lake Superior Chippewa*

*Comment:* The Band urged a fair, scientifically sound, and feasible process for all stakeholders, including affected and surrounding communities. The taconite industry should not be allowed to dictate its own compliance schedule or prolong compliance with Federal laws and regulations.

*Response:* EPA agrees with this comment and has implemented a process to establish final BART limits based upon the most current, relevant, and scientifically sound information available. The taconite plant owners were in a unique position to acquire and provide the needed scientific information and understandably had motivation to do so. However, they are not dictating their own compliance schedule.

*Comment:* The Band argued that the emission limits in the 2013 FIP are more reasonable in terms of protecting visibility than the limits proposed in the revised FIP.

*Response:* While we acknowledge that a few of the emission limits in the 2013 FIP were more stringent than the limits in our proposed FIP revision, and were thus more protective of visibility, we disagree that the original limits were more reasonable. For the reasons explained in our proposal, new information provided by the taconite companies shows that the technology on which the 2013 FIP limits were based, high-stoichiometric LNBs, would adversely affect pellet quality. As a result, we proposed new BART determinations based on new technologies. These technologies will still result in significant emission reductions, improving visibility in the Class I areas in Minnesota and Michigan.

*Comment:* The Band stated that the compliance schedule in the 2013 FIP was more reasonable from a health protection standpoint. The Band stated that it preferred the 2013 FIP schedule over the longer compliance schedule in the proposed FIP revision. Alternatively, a compromise schedule between the original schedule and the proposed schedule would be acceptable.

*Response:* Please see our response to a similar comment from NPCA.

*Comment:* The Band stated that Eastern bituminous coals are available that could meet both the requirements for a low-sulfur coal (0.66%) and a very high heating value (US DOE, NETL, Detailed Coal Specifications, Quality Guidelines for Energy System Studies, Final Report, DOE/NETL-401/012111, January 2012, page 31).

*Response:* Please see our response to a similar comment from the Forest Service.

*Comment:* The Band stated that SCR is considered the best available retrofit technology that has been used at other coal facilities and could feasibly reduce NO<sub>x</sub> emissions for taconite furnaces. The Band agreed with the National Park Service that the use of tail-end SCR with steam reheat should be evaluated for BART.

*Response:* Please see our response to a similar comment from the National Park Service.

*Comment:* The Band noted that EPA proposed to set limits for United Taconite and Tilden of 3.0 lbs NO<sub>x</sub>/MMBTU when burning natural gas and 2.5 lbs NO<sub>x</sub>/MMBTU when burning a gas/coal mix if the presumptive limits of 2.8 lbs NO<sub>x</sub>/MMBTU and 1.5 lbs NO<sub>x</sub>/MMBTU, respectively, cannot be met.

The Band noted that a limit of 2.5 lbs NO<sub>x</sub>/MMBTU (gas coal mix) is 67 percent higher than the predicted emission rate of 1.5 lbs NO<sub>x</sub>/MMBTU. The Band acknowledged that some uncertainty is involved in developing the use of a new control technology, but argued that this range of emission limits is too large.

*Response:* Please see our response to a similar comment from the National Park Service.

*Comment:* The Band stated that EPA recently implemented a national policy on Environmental Justice for Working with Federally Recognized Tribes and Indigenous Peoples. EPA must uphold its duties to protect the interests of tribes and their treaty rights and explain how the proposed FIP complies with EPA's existing guidance and policies with Federally Recognized Tribes and Indigenous Peoples.

*Response:* The U.S. Constitution defines treaties as part of the supreme law of the land with the same legal force as Federal statutes. Treaties are to be interpreted in accordance with the Federal Indian canons of construction, a set of long-standing principles developed by courts to guide the interpretation of treaties between the U.S. government and Indian tribes. As the Supreme Court has explained, treaties should be construed liberally in favor of tribes, giving effect to the treaty terms as tribes would have understood them, with ambiguous provisions interpreted for their benefit. Only Congress may abrogate Indian treaty rights, and courts will not find that abrogation has occurred absent clear evidence of congressional intent.

EPA has committed to consider all relevant information obtained during tribal consultation to help ensure that EPA's actions do not conflict with treaty rights, to help ensure that EPA is fully informed when it seeks to implement its programs, and to further protect treaty rights and resources when it has discretion to do so. We have done so in this action. EPA consulted and coordinated with tribal officials and provided information on both the 2012 FIP proposal and the current taconite FIP proposal early in the process of developing this regulation in order to allow tribal governments to have meaningful and timely input. EPA provided information to tribes on the rationale for proposing this regulation in the absence of the states submitting plans, the potential health and environmental impacts associated with these facilities, and the emissions reductions to be gained from implementing this regulation. EPA also took into consideration the concerns

and needs identified by tribal governments during this process. These consultation and education and outreach efforts began in August 2012 and continue through the present utilizing forums such as monthly tribe-EPA conference calls, presentations during annual meetings and conferences, and one-to-one discussions with EPA subject matter experts as requested.

EPA's revision of the FIP is expected to have significant environmental benefits relative to the SIPs submitted by Michigan and Minnesota. On- and off-reservation trust resources held by Minnesota tribes (and other tribes), as recognized in treaties and in *Minnesota v. Mille Lacs Band*, 526 U.S. 172 (1999), among other authorities, will be protected to a greater extent by the controls required in the amended FIP.

#### F. Comments by ArcelorMittal

*Comment:* ArcelorMittal cited to the preamble to the proposed FIP revision, which states that "there are no significant costs or environmental impacts" associated with the BART determinations for Hibbing and Minorca. However, in actuality, the changes necessary to meet the proposed emission limits will not be without costs and environmental impacts. ArcelorMittal will be required to expend millions of dollars to design and implement changes to its straight-grate furnaces. It will also incur substantial costs associated with lost production during downtime and shakedown when these technologies are installed. Once operational, fuel penalties are expected which will result in increased cost.

*Response:* EPA acknowledges that there will be costs associated with the BART control technologies employed by ArcelorMittal. EPA's full statement in the preamble was that "there are no significant costs or environmental impacts associated with this technology that would necessitate its elimination from consideration as BART." EPA continues to believe that the costs, energy, and non-air quality impacts associated with the selected BART controls are reasonable.

#### G. Comments by United States Steel

U.S. Steel submitted the following comments to ensure that EPA's approach to amending the original FIP is applied evenly and fairly and results in a consistent approach to BART for the taconite industry.

*Comment:* U.S. Steel agreed with EPA's decision to develop a case-by-case approach to BART for indurating furnaces and the Agency's proposed approach to determining BART for each

individual affected unit, based upon that unit's design and unit-specific characteristics.

*Response:* EPA appreciates U.S. Steel's support.

*Comment:* U.S. Steel stated that a similar approach will be necessary for U.S. Steel's Minntac and Keetac furnaces.

*Response:* This comment is outside the scope of this rulemaking.

*Comment:* U.S. Steel stated that EPA should consider delaying finalization of the proposed FIP revision until EPA is prepared to promulgate similar amendments for all furnaces in the taconite industry.

*Response:* EPA is bound by a settlement agreement to finalize the proposed FIP revision by March 18, 2016. Furthermore, there have already been considerable delays in the implementation of BART for taconite indurating furnaces.

*Comment:* U.S. Steel stated that if EPA does not delay finalization of the proposed FIP revision, EPA should continue the stay of effective dates in the original 2013 FIP pending completion of a similar FIP amendment for U.S. Steel's Minntac and Keetac facilities.

*Response:* This comment is outside the scope of this rulemaking.

*Comment:* U.S. Steel stated that EPA should clarify that U.S. Steel is part owner of Hibbing taconite.

*Response:* EPA acknowledges that U.S. Steel is a part owner of the Hibbing facility.

*Comment:* U.S. Steel identified four points made by EPA with which U.S. Steel disagrees and could not find substantiating information in the docket. These points are: (1) The smaller preheat burners at Minntac achieve very low NO<sub>x</sub> emissions rates (0.1–0.3 lbs NO<sub>x</sub>/MMBTU) due to a more favorable NO<sub>x</sub> reduction combustion environment in the preheat zone as compared to the firing end of the kiln; (2) ported kilns significantly change the heat balance of the furnace; (3) differences in the magnetite content of the ore body used by Minntac and United Taconite are significant; and (4) high-stoichiometric LNBs will require more fuel and result in higher NO<sub>x</sub> emissions.

*Response:* The basis for the above points questioned by U.S. Steel is presented in the proposed FIP at 80 FR 64163, which is in turn based upon the November 26, 2013 declaration by Eric Wagner, the Manager of Process Engineering for Metso Minerals Pyro Division, a "global expert in the design of iron ore pelletizing furnaces." This declaration is attached to Cliffs' November 26, 2013 Petition for

Administrative Reconsideration of the Partial Disapproval of Air Quality Implementation Plans for Regional Haze for the States of Michigan and Minnesota. Although a hard copy of this document was included in EPA's Regional docket, and available for inspection at EPA's Region 5 office, EPA mistakenly did not include this Petition for Reconsideration in the electronic docket for this rule until after the comment period had closed. U.S. Steel's comment questions the basis for several of Eric Wagner's statements regarding factors affecting indurating furnace operation and NO<sub>x</sub> emissions. We do not believe this omission was material, however, because U.S. Steel is seeking information, not challenging or suggesting revisions to the proposal.

*Comment:* U.S. Steel stated that EPA should reconsider the partial disapproval of Minnesota's SIP.

*Response:* This comment is outside the scope of this rulemaking.

*Comment:* U.S. Steel stated that, for each of the affected facilities, there is a schedule prescribed for installation of the technology and period to collect data to confirm or adjust the limit based upon the data. The period allows for eight months of data collection. If an affected facility elects to install the technology earlier than prescribed by rule, the facility should have the ability to utilize a more robust data set greater than the eight months specified. Due to seasonal variations, a facility should have the ability to use at a minimum 12 months of data if the installation of technology occurs prior to the compliance date.

*Response:* This notice is intended to capture the details agreed upon by EPA, Cliffs and ArcelorMittal in a settlement agreement. This comment comes from a commenter who was not party to the settlement agreement. The detailed compliance schedules contained in the proposed FIP are based upon the settlement terms agreed to by Cliffs and ArcelorMittal, who operate all of the taconite furnaces subject to this FIP. The eight month testing period that was originally proposed was considered by them to be of sufficient duration to evaluate the performance of their control systems and their effect on pellet quality. There is therefore no benefit to extending the testing period when such an extension is not necessary. The requirements of BART, and not the compliance schedule in this rule, establish the most appropriate compliance schedule to be followed by any other taconite facility.

*Comment:* U.S. Steel supported the provision allowing Tilden to exclude emissions data during a natural gas

curtailment that is beyond a facility's control. These events are typically infrequent, unplanned, and may cause the facility to operate in a manner that is not typical.

*Response:* EPA appreciates U.S. Steel's support for the provision stating that the SO<sub>2</sub> limit for Tilden's grate kiln does not apply during a natural gas curtailment.

#### **IV. Revision to Equation for Normally Distributed but Not Statistically Independent Data**

The proposal describes the process for establishing final emission limits to which the identified facilities shall become subject. As discussed in the proposal, the final limit must be based on the 95 percent upper predictive limit (UPL) using CEMS data compiled over an eight-month testing period. The UPL is a statistical technique that examines an existing set of data points and predicts the chances (*i.e.*, the probability) of future data points (in this case, emission rates). In general terms, the UPL is a value that is calculated from a data set that identifies the emission rate that a source is meeting and would be expected to meet a specified percent of the time that the source is operating. In this case, the UPL will be the emission rate that the taconite facilities are predicted to be below during 95 out of 100 720-hour averaging periods. The UPL will be based on data obtained during an eight-month testing period during which Cliffs and ArcelorMittal are primarily focused on operating the controls in a manner that does not adversely affect pellet quality, with a wide variability in emissions expected. The UPL must be calculated using an equation based on the average and variance of a data set, the distribution of the data, the quantity of data points, and the compliance period (*e.g.*, a 720-hour compliance period).

The settlement agreement and proposed FIP specified three equations for determining the UPL depending upon whether the data are normally distributed and, if so, whether the data are statistically independent or not statistically independent. In the proposal (the equation numbers have been changed in the final), Equation 1 applied to normally distributed, statistically independent data sets; Equation 3 applied to normally distributed, but not statistically independent data sets; and Equation 4, the non-parametric UPL equation, applied to data sets that do not conform to a specific distribution. EPA's statistical guidance for environmental applications, the ProUCL User Guide,

includes UPL equations for different types of distributions, as well as a non-parametric equation for data sets that do not conform to a specific distribution. The guidance does not, however, include an equation for normally distributed, but not statistically independent (that is, highly correlated) data. Because Cliffs and ArcelorMittal were concerned about this latter category of data, we proposed what was purported to be an appropriate equation for normally distributed, but not statistically independent data (Equation 3). We subsequently found that Equation 3 is not valid for large data sets, which is what will result from eight months of hourly data. When we applied Equation 3 to a large data set, the resulting UPL was higher than the highest 720-hour average, a nonsensical and mathematically unreasonable result. We are therefore eliminating Equation 3 from the final FIP. Instead, we are requiring use of the fall back non-parametric equation (Equation 4) for data that are normally distributed, but not statistically independent.

We are finalizing the non-parametric equation contained in the proposal with a clarification regarding the appropriate data set to be used. As stated above, the UPL equations are used to determine emission limits. To correctly calculate the UPL using the non-parametric equation, the data that is ranked from smallest to highest must be in the same form as the emission limit. The final emission limits are expressed in terms of 720-hour averages, so the ranked data set used in the non-parametric equation must be a set of 720-hour averages as well. Using data sets based upon an averaging time inconsistent with the

form of the emission limit would be an improper use of the equation. For instance, calculating the 95 percent non-parametric limit using a data set of ranked one-hour values would establish the emission rate (based upon a one-hour average) that the source would be predicted to be below during 95 out of 100 one-hour averaging periods, *i.e.*, an emission limit based on hourly compliance. The resulting emission limit would be improper if compliance is to be based upon a 720-hour average. Based upon our evaluation of existing data sets, using the 95th percentile of the one-hour values to establish a 720-hour average emission limit would result in a limit that is higher than the highest 720-hour average in the data sets, which is clearly inconsistent with the purpose of a 95 percent UPL.

To reiterate, the purpose of a 95 percent UPL is to establish an emission rate that a source is predicted to be below during 95 out of 100 averaging periods. Importantly, however, this does not mean that the source would be expected to exceed its emission limit five percent of the time once the limit is in place. During the eight-month testing period, Cliffs and ArcelorMittal will operate their furnaces and the new control technologies in a manner that will not interfere with pellet quality. The furnace operators will be adjusting numerous variables to optimize control technology performance, which will result in higher emissions at times. These periods of higher emissions will factor into the UPL calculation. Once the eight-month testing period is over, however, the operators will have gained sufficient experience to run the furnaces and control technologies with fewer

adjustments, meaning less emission variations and lower emissions overall. Using the 95 percent UPL ensures that the final emission limits will be consistent with the actual emission reduction capabilities of the BART controls, as required by 40 CFR 51.301, which defines BART as “the degree of reduction achievable.” We also note that the 720-hour averaging period for the final emission limits will provide considerable flexibility for the sources. The operators will be able to continually review CEMS data on an hourly basis and make any necessary adjustments over the remaining 719 hours to ensure compliance.

**V. What action is EPA taking?**

For the reasons stated in the proposed FIP revision and the response to comments, EPA is finalizing the new BART emission limits and related requirements for taconite furnaces as proposed, with two exceptions. First, EPA is revising the requirement to report CEMS and pellet quality data at the end of a period that did not fall within the preceding calendar quarter from within 7 days of the close of the period to within 30 days of the close of the period. This revision will allow the facilities sufficient time to complete the appropriate laboratory analyses and quality assurance for the data and will not significantly interfere with expeditiously setting the final limits. Second, EPA is replacing the incorrect equation for normally distributed but not statistically independent data with the non-parametric UPL equation, which is consistent with EPA guidance. A summary of our final decision is included in the table below.

SUMMARY OF FINAL EMISSION LIMITS AND COMPLIANCE SCHEDULES

Source	Compliance schedule (months)	NO <sub>x</sub> limit for gas/coal mix (lbs/MMBtu)	NO <sub>x</sub> limit for gas only (lbs/MMBtu)	SO <sub>2</sub> limit
Tilden .....	60	1.5–2.5	2.8–3.0	500 lbs/hr and 0.6%S.
Hibbing 1 .....	37	.....	1.2–1.8	
Hibbing 2 .....	55	.....	1.2–1.8	
Hibbing 3 .....	60	.....	1.2–1.8	
UTAC 1 .....	37	1.5–2.5	2.8–3.0	529 lbs/hr (combined L1&2) and 1.5%S.
UTAC 2 .....	55	1.5–2.5	2.8–3.0	
Minorca Mine .....	55	.....	1.2–1.8	

**VI. Statutory and Executive Order Reviews**

Additional information about these statutes and Executive Orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

*A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review*

This action is exempt from review by the Office of Management and Budget (OMB) because it is a rule of particular applicability and only affects four facilities.

*B. Paperwork Reduction Act (PRA)*

This action does not impose an information collection burden under the PRA. Because the FIP applies to just four facilities, the Paperwork Reduction Act does not apply. See 5 CFR 1320.3(c).

### C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. EPA's rule adds additional controls to certain sources. The Regional Haze FIP revisions that EPA is promulgating here would impose Federal control requirements to meet the BART requirement for NO<sub>x</sub> and SO<sub>2</sub> emissions on specific units at three sources in Minnesota and one in Michigan. The net result of the FIP action is that EPA is requiring emission controls on the indurating furnaces at four taconite furnaces and none of these sources are owned by small entities, and therefore are not small entities.

### D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

### E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

### F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments. Thus, Executive Order 13175 does not apply to this rule. However, EPA did discuss this action on a number of occasions, including a June 28, 2015, conference call with the Michigan and Minnesota tribes.

### G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not

economically significant as defined in Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. However, to the extent this rule will limit emissions of NO<sub>x</sub> and SO<sub>2</sub>, the rule will have a beneficial effect on children's health by reducing air pollution.

### H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

### I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

### J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations. We have determined that this rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population.

### K. Congressional Review Act (CRA)

This rule is exempt from the CRA because it is a rule of particular applicability.

### L. Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 13, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to

enforce its requirements. (See section 307(b)(2).)

### List of Subjects in 40 CFR Part 52

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

Dated: March 18, 2016.

**Gina McCarthy,**  
Administrator.

For the reasons stated in the preamble, 40 CFR chapter I is amended as follows:

### PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

■ 2. Section 52.1183 is amended by revising paragraphs (k), (l), (m), and (n) and adding paragraph (p) to read as follows:

#### § 52.1183 Visibility protection.

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(k) Tilden Mining Company, or any subsequent owner/operator of the Tilden Mining Company facility in Ishpeming, Michigan, shall meet the following requirements:

(1) *NO<sub>x</sub> Emission Limits.* (i) An emission limit of 2.8 lbs NO<sub>x</sub>/MMBTU, based on a 720-hour rolling average, shall apply to Tilden Grate Kiln Line 1 when burning natural gas, and an emission limit of 1.5 lbs NO<sub>x</sub>/MMBTU, based on a 720-hour rolling average, shall apply to Tilden Grate Kiln Line 1 when burning coal or a mixture of coal and natural gas. These emission limits will become enforceable 60 months after May 12, 2016 and only after EPA's confirmation or modification of the emission limit in accordance with the procedures set forth in paragraphs (k)(1)(i) through (viii) of this section.

(ii) Compliance with these emission limits shall be demonstrated with data collected by a continuous emissions monitoring system (CEMS) for NO<sub>x</sub>. The owner or operator must start collecting CEMS data for NO<sub>x</sub> upon May 12, 2016 and submit the data to EPA no later than 30 days from the end of each calendar quarter. Any remaining data through the end of the 57th month from May 12, 2016, that does not fall within a calendar quarter, must be submitted to EPA no later than 30 days from the end of the 57th month. Although CEMS data must continue to be collected, it does

not need to be submitted to EPA starting 57 months after May 12, 2016.

(iii) No later than 48 months from May 12, 2016, the owner or operator must submit to EPA a report, including any final report(s) completed by the selected NO<sub>x</sub> reduction technology supplier and furnace retrofit engineer, containing a detailed engineering analysis and modeling of the NO<sub>x</sub> reduction control technology being installed on Tilden Grate Kiln Line 1. This report must include a list of all variables that can reasonably be expected to have an impact on NO<sub>x</sub> emission control technology performance, as well as a description of how these variables can be adjusted to reduce NO<sub>x</sub> emissions to meet the NO<sub>x</sub> design emission limit. This NO<sub>x</sub> reduction control technology must be designed to meet emission limits of 2.8 lbs NO<sub>x</sub>/MMBTU when burning natural gas and 1.5 lbs NO<sub>x</sub>/MMBTU when burning coal or a mixture of coal and natural gas.

(iv) The NO<sub>x</sub> reduction control technology shall be installed on Tilden Grate Kiln Line 1 furnace no later than 50 months from May 12, 2016.

(v) Commencing on the earlier of: Six months from the installation of the NO<sub>x</sub> reduction control technology or 50 months from May 12, 2016, the owner or operator must provide to EPA the results from pellet quality analyses. The owner or operator shall provide the results from pellet quality analyses no later than 30 days from the end of each calendar quarter up until 57 months after May 12, 2016. Any remaining results through the end of the 57th month that do not fall within a calendar quarter must be submitted to EPA no later than 30 days from the end of the 57th month. The pellet quality analyses shall include results for the following factors: Compression, reducibility, before tumble, after tumble, and low temperature disintegration. For each of the pellet quality analysis factors the owner or operator must explain the pellet quality analysis factor as well as the defined acceptable range for each factor using the applicable product quality standards based upon customers' pellet specifications that are contained in Tilden's ISO 9001 quality management system. The owner or operator shall provide pellet quality analysis testing results that state the date and time of the analysis and, in order to define the time period when pellets were produced outside of the defined acceptable range for the pellet quality factors listed, provide copies of the production logs that document the starting and ending times for such periods. The owner or operator shall

provide an explanation of causes for pellet samples that fail to meet the acceptable range for any pellet quality analysis factor. Pellet quality information and data may be submitted to EPA as Confidential Business Information.

(vi) No later than 57 months after May 12, 2016, the owner or operator may submit to EPA a report to either confirm or modify the NO<sub>x</sub> limits for Tilden Grate Kiln Line 1 within the upper and lower bounds described below. EPA will review the report and either confirm or modify the NO<sub>x</sub> limits. If the CEMS data collected during operating periods between months 50 and 57 that both meet pellet quality specifications and proper furnace/burner operation is normally distributed, the limit adjustment determination shall be based on the appropriate (depending upon whether data are statistically independent or dependent) 95% upper predictive limit (UPL) equations in paragraph (p) of this section. If the CEMS data collected during operating periods between months 50 and 57 that both meet pellet quality specifications and proper furnace/burner operation are not normally distributed, the limit adjustment determination shall be based on the non-parametric equation provided in paragraph (p) of this section. The data set for the determination shall exclude periods when pellet quality did not fall within the defined acceptable ranges of the pellet quality factors identified pursuant to paragraph (k)(1)(v) of this section and for any subsequent period when production had been reduced in response to pellet quality concerns consistent with Tilden's ISO 9001 operating standards. Any excluded period will commence at the time documented on the production log demonstrating pellet quality did not fall within the defined acceptable range and shall end when pellet quality within the defined acceptable range has been re-established at planned production levels, which will be presumed to be the level that existed immediately prior to the reduction in production due to pellet quality concerns. EPA may also exclude data where operations are inconsistent with the reported design parameters of the NO<sub>x</sub> reduction control technology that were installed.

(vii) EPA will take final agency action by publishing its final confirmation or modification of the NO<sub>x</sub> limits in the **Federal Register** no later than 60 months after May 12, 2016. The confirmed or modified NO<sub>x</sub> limit for Tilden Grate Kiln Line 1 when burning only natural gas may be no lower than 2.8 lbs NO<sub>x</sub>/MMBTU, based on a 720-

hour rolling average, and may not exceed 3.0 lbs NO<sub>x</sub>/MMBTU, based on a 720-hour rolling average. The confirmed or modified NO<sub>x</sub> limit for Tilden Grate Kiln Line 1 when burning coal or a mixture of coal and natural gas may be no lower than 1.5 lbs NO<sub>x</sub>/MMBTU, based on a 720-hour rolling average, and may not exceed 2.5 lbs NO<sub>x</sub>/MMBTU, based on a 720-hour rolling average.

(viii) If the owner or operator submits a report proposing a single NO<sub>x</sub> limit for all fuels, EPA may approve the proposed NO<sub>x</sub> limit for all fuels based on a 30-day rolling average. The confirmed or modified limit will be established and enforceable within 60 months from May 12, 2016.

(2) *SO<sub>2</sub> Emission Limits.* A fuel sulfur content limit of no greater than 1.20 percent sulfur content by weight shall apply to fuel combusted in Process Boiler #1 (EUBOILER1) and Process Boiler #2 (EUBOILER2) beginning three months from March 8, 2013. A fuel sulfur content limit of no greater than 1.50 percent sulfur content by weight shall apply to fuel combusted in the Line 1 Dryer (EUDRYER1) beginning 3 months from March 8, 2013. The sampling and calculation methodology for determining the sulfur content of fuel must be described in the monitoring plan required at paragraph (n)(8)(x) of this section.

(3) The owner or operator of the Tilden Grate Kiln Line 1 furnace shall meet an emission limit of 500 lbs SO<sub>2</sub>/hr based on a 30-day rolling average beginning six months after May 12, 2016. Compliance with these emission limits shall be demonstrated with data collected by a continuous emissions monitoring system (CEMS) for SO<sub>2</sub>. The owner or operator must start collecting CEMS data for SO<sub>2</sub> beginning six months after May 12, 2016 and submit the data to EPA no later than 30 days from the end of each calendar quarter. The Tilden Grate Kiln Line 1 furnace shall not be limited to natural gas fuel. Beginning six months after May 12, 2016, any coal burned on Tilden Grate Kiln Line 1 shall have no more than 0.60 percent sulfur by weight based on a monthly block average. The sampling and calculation methodology for determining the sulfur content of coal must be described in the monitoring plan required for this furnace. The owner or operator must calculate an SO<sub>2</sub> limit based on 12 continuous months of CEMS emissions data and submit such limit, calculations, and CEMS data to EPA no later than 36 months after May 12, 2016. If the submitted CEMS SO<sub>2</sub> hourly data are normally distributed, the SO<sub>2</sub> lbs/hr emission rate shall be



based on the appropriate (depending upon whether data are statistically independent or dependent) 99% upper predictive limit (UPL) equation. If the submitted CEMS SO<sub>2</sub> hourly data are not normally distributed, the SO<sub>2</sub> lbs/hr emission rate shall be based on the non-parametric equation provided in paragraph (p) of this section.

Compliance with the SO<sub>2</sub> lbs/hr emission rate shall be determined on a 30-day rolling average basis. EPA will take final agency action by publishing a confirmation or modification of the SO<sub>2</sub> limit in the **Federal Register** no later than 39 months after May 12, 2016. EPA may adjust the 500 lbs SO<sub>2</sub>/hr limit downward to reflect the calculated SO<sub>2</sub> emission rate; however, EPA will not increase the SO<sub>2</sub> limit above 500 lbs SO<sub>2</sub>/hr.

(4) Starting 26 months from May 12, 2016, records shall be kept for any day during which fuel oil is burned as fuel (either alone or blended with other fuels) in Grate Kiln Line 1. These records must include, at a minimum, the gallons of fuel oil burned per hour, the sulfur content of the fuel oil, and the SO<sub>2</sub> emissions in pounds per hour.

(5) Starting 26 months from May 12, 2016, the SO<sub>2</sub> limit for Grate Kiln Line 1 does not apply for any hour in which it is documented that there is a natural gas curtailment beyond Cliffs' control necessitating that the supply of natural gas to Tilden's Line 1 indurating furnace is restricted or eliminated. Records must be kept of the cause of the curtailment and duration of such curtailment. During such curtailment, the use of backup coal is restricted to coal with no greater than 0.60 percent sulfur by weight.

(l) *Testing and monitoring.* (1) The owner or operator shall install, certify, calibrate, maintain, and operate a CEMS for NO<sub>x</sub> on Tilden Grate Kiln Line 1. Compliance with the emission limits for NO<sub>x</sub> shall be determined using data from the CEMS.

(2) The owner or operator shall install, certify, calibrate, maintain, and operate a CEMS for SO<sub>2</sub> on Tilden Grate Kiln Line 1. Compliance with the emission standard selected for SO<sub>2</sub> shall be determined using data from the CEMS.

(3) The owner or operator shall install, certify, calibrate, maintain, and operate one or more continuous diluent monitor(s) (O<sub>2</sub> or CO<sub>2</sub>) and continuous flow rate monitor(s) on Tilden Grate Kiln Line 1 to allow conversion of the NO<sub>x</sub> and SO<sub>2</sub> concentrations to units of the standard (lbs/MMBTU and lbs/hr, respectively) unless a demonstration is made that a diluent monitor and continuous flow rate monitor are not

needed for the owner or operator to demonstrate compliance with applicable emission limits in units of the standards.

(4) For purposes of this section, all CEMS required by this section must meet the requirements of paragraphs (l)(4)(i) through (xiv) of this section.

(i) All CEMS must be installed, certified, calibrated, maintained, and operated in accordance with 40 CFR part 60, appendix B, Performance Specification 2 (PS-2) and appendix F, Procedure 1.

(ii) All CEMS associated with monitoring NO<sub>x</sub> (including the NO<sub>x</sub> monitor and necessary diluent and flow rate monitors) must be installed and operational upon May 12, 2016. All CEMS associated with monitoring SO<sub>2</sub> must be installed and operational no later than six months after May 12, 2016. Verification of the CEMS operational status shall, as a minimum, include completion of the manufacturer's written requirements or recommendations for installation, operation, and calibration of the devices.

(iii) The owner or operator must conduct a performance evaluation of each CEMS in accordance with 40 CFR part 60, appendix B, PS-2. The performance evaluations must be completed no later than 60 days after the respective CEMS installation.

(iv) The owner or operator of each CEMS must conduct periodic Quality Assurance, Quality Control (QA/QC) checks of each CEMS in accordance with 40 CFR part 60, appendix F, Procedure 1. The first CEMS accuracy test will be a relative accuracy test audit (RATA) and must be completed no later than 60 days after the respective CEMS installation.

(v) The owner or operator of each CEMS must furnish the Regional Administrator two, or upon request, more copies of a written report of the results of each performance evaluation and QA/QC check within 60 days of completion.

(vi) The owner or operator of each CEMS must check, record, and quantify the zero and span calibration drifts at least once daily (every 24 hours) in accordance with 40 CFR part 60, appendix F, Procedure 1, Section 4.

(vii) Except for CEMS breakdowns, repairs, calibration checks, and zero and span adjustments, all CEMS required by this section shall be in continuous operation during all periods of process operation of the indurating furnaces, including periods of process unit startup, shutdown, and malfunction.

(viii) All CEMS required by this section must meet the minimum data

requirements at paragraphs (l)(4)(viii)(A) through (C) of this section.

(A) Complete a minimum of one cycle of operation (sampling, analyzing, and data recording) for each successive 15-minute quadrant of an hour.

(B) Sample, analyze, and record emissions data for all periods of process operation except as described in paragraph (l)(4)(viii)(C) of this section.

(C) When emission data from CEMS are not available due to continuous monitoring system breakdowns, repairs, calibration checks, or zero and span adjustments, emission data must be obtained using other monitoring systems or emission estimation methods approved by the EPA. The other monitoring systems or emission estimation methods to be used must be incorporated into the monitoring plan required by this section and provide information such that emissions data are available for a minimum of 18 hours in each 24-hour period and at least 22 out of 30 successive unit operating days.

(ix) Owners or operators of each CEMS required by this section must reduce all data to 1-hour averages. Hourly averages shall be computed using all valid data obtained within the hour but no less than one data point in each 15-minute quadrant of an hour. Notwithstanding this requirement, an hourly average may be computed from at least two data points separated by a minimum of 15 minutes (where the unit operates for more than one quadrant in an hour) if data are unavailable as a result of performance of calibration, quality assurance, preventive maintenance activities, or backups of data from data acquisition and handling systems and recertification events.

(x) The 30-day rolling average emission rate determined from data derived from the CEMS required by this section (in lbs/MMBTU or lbs/hr depending on the emission standard selected) must be calculated in accordance with paragraphs (l)(4)(x)(A) through (F) of this section.

(A) Sum the total pounds of the pollutant in question emitted from the unit during an operating day and the previous 29 operating days.

(B) Sum the total heat input to the unit (in MMBTU) or the total actual hours of operation (in hours) during an operating day and the previous 29 operating days.

(C) Divide the total number of pounds of the pollutant in question emitted during the 30 operating days by the total heat input (or actual hours of operation depending on the emission limit selected) during the 30 operating days.

(D) For purposes of this calculation, an operating day is any day during

which fuel is combusted in the BART affected unit regardless of whether pellets are produced. Actual hours of operation are the total hours a unit is firing fuel regardless of whether a complete 24-hour operational cycle occurs (*i.e.*, if the furnace is firing fuel for only five hours during a 24-hour period, then the actual operating hours for that day are five. Similarly, total number of pounds of the pollutant in question for that day is determined only from the CEMS data for the five hours during which fuel is combusted.)

(E) If the owner or operator of the CEMS required by this section uses an alternative method to determine 30-day rolling averages, that method must be described in detail in the monitoring plan required by this section. The alternative method will only be applicable if the final monitoring plan and the alternative method are approved by EPA.

(F) A new 30-day rolling average emission rate must be calculated for the period ending each new operating day.

(xi) The 720-hour rolling average emission rate determined from data derived from the CEMS required by this section (in lbs/MMBTU) must be calculated in accordance with paragraphs (l)(4)(xi)(A) through (C) of this section.

(A) Sum the total pounds of NO<sub>x</sub> emitted from the unit every hour and the previous (not necessarily consecutive) 719 hours for which that type of fuel (either natural gas or mixed coal and natural gas) was used.

(B) Sum the total heat input to the unit (in MMBTU) every hour and the previous (not necessarily consecutive) 719 hours for which that type of fuel (either natural gas or mixed coal and natural gas) was used.

(C) Divide the total number of pounds of NO<sub>x</sub> emitted during the 720 hours, as defined above, by the total heat input during the same 720-hour period. This calculation must be done separately for each fuel type (either for natural gas or mixed coal and natural gas).

(xii) Data substitution must not be used for purposes of determining compliance under this regulation.

(xiii) All CEMS data shall be reduced and reported in units of the applicable standard.

(xiv) A Quality Control Program must be developed and implemented for all CEMS required by this section in accordance with 40 CFR part 60, appendix F, Procedure 1, Section 3. The program will include, at a minimum, written procedures and operations for calibration checks, calibration drift adjustments, preventative maintenance, data collection, recording and reporting,

accuracy audits/procedures, periodic performance evaluations, and a corrective action program for malfunctioning CEMS.

(m) *Recordkeeping requirements.*

(1)(i) Records required by this section must be kept in a form suitable and readily available for expeditious review.

(ii) Records required by this section must be kept for a minimum of five years following the date of creation.

(iii) Records must be kept on site for at least two years following the date of creation and may be kept offsite, but readily accessible, for the remaining three years.

(2) The owner or operator of the BART affected unit must maintain the records identified in paragraphs (m)(2)(i) through (xi) of this section.

(i) A copy of each notification and report developed for and submitted to comply with this section including all documentation supporting any initial notification or notification of compliance status submitted, according to the requirements of this section.

(ii) Records of the occurrence and duration of each startup, shutdown, and malfunction of the BART affected unit, air pollution control equipment, and CEMS required by this section.

(iii) Records of activities taken during each startup, shutdown, and malfunction of the BART affected unit, air pollution control equipment, and CEMS required by this section.

(iv) Records of the occurrence and duration of all major maintenance conducted on the BART affected unit, air pollution control equipment, and CEMS required by this section.

(v) Records of each excess emission report, including all documentation supporting the reports, dates and times when excess emissions occurred, investigations into the causes of excess emissions, actions taken to minimize or eliminate the excess emissions, and preventative measures to avoid the cause of excess emissions from occurring again.

(vi) Records of all CEMS data including, as a minimum, the date, location, and time of sampling or measurement, parameters sampled or measured, and results.

(vii) All records associated with quality assurance and quality control activities on each CEMS as well as other records required by 40 CFR part 60, appendix F, Procedure 1 including, but not limited to, the quality control program, audit results, and reports submitted as required by this section.

(viii) Records of the NO<sub>x</sub> emissions during all periods of BART affected unit operation, including startup, shutdown, and malfunction, in the units of the

standard. The owner or operator shall convert the monitored data into the appropriate unit of the emission limitation using appropriate conversion factors and F-factors. F-factors used for purposes of this section shall be documented in the monitoring plan and developed in accordance with 40 CFR part 60, appendix A, Method 19. The owner or operator may use an alternate method to calculate the NO<sub>x</sub> emissions upon written approval from EPA.

(ix) Records of the SO<sub>2</sub> emissions or records of the removal efficiency (based on CEMS data), depending on the emission standard selected, during all periods of operation, including periods of startup, shutdown, and malfunction, in the units of the standard.

(x) Records associated with the CEMS unit including type of CEMS, CEMS model number, CEMS serial number, and initial certification of each CEMS conducted in accordance with 40 CFR part 60, appendix B, Performance Specification 2 must be kept for the life of the CEMS unit.

(xi) Records of all periods of fuel oil usage as required in paragraph (k)(4) of this section.

(n) *Reporting requirements.* (1) All requests, reports, submittals, notifications, and other communications to the Regional Administrator required by this section shall be submitted, unless instructed otherwise, to the Air and Radiation Division, U.S. Environmental Protection Agency, Region 5 (A-18J) at 77 West Jackson Boulevard, Chicago, Illinois 60604. References in this section to the Regional Administrator shall mean the EPA Regional Administrator for Region 5.

(2) The owner or operator of each BART affected unit identified in this section and CEMS required by this section must provide to the Regional Administrator the written notifications, reports, and plans identified at paragraphs (n)(2)(i) through (viii) of this section. If acceptable to both the Regional Administrator and the owner or operator of each BART affected unit identified in this section and CEMS required by this section the owner or operator may provide electronic notifications, reports, and plans.

(i) A notification of the date construction of control devices and installation of burners required by this section commences postmarked no later than 30 days after the commencement date.

(ii) A notification of the date the installation of each CEMS required by this section commences postmarked no later than 30 days after the commencement date.

(iii) A notification of the date the construction of control devices and installation of burners required by this section is complete postmarked no later than 30 days after the completion date.

(iv) A notification of the date the installation of each CEMS required by this section is complete postmarked no later than 30 days after the completion date.

(v) A notification of the date control devices and burners installed by this section startup postmarked no later than 30 days after the startup date.

(vi) A notification of the date CEMS required by this section postmarked no later than 30 days after the startup date.

(vii) A notification of the date upon which the initial CEMS performance evaluations are planned. This notification must be submitted at least 60 days before the performance evaluation is scheduled to begin.

(viii) A notification of initial compliance signed by the responsible official, who shall certify its accuracy, attesting to whether the source has complied with the requirements of this section, including, but not limited to, applicable emission standards, control device and burner installations, and CEMS installation and certification. This notification must be submitted before the close of business on the 60th calendar day following the completion of the compliance demonstration and must include, at a minimum, the information in paragraphs (n)(2)(viii)(A) through (F) of this section.

(A) The methods used to determine compliance.

(B) The results of any CEMS performance evaluations and other monitoring procedures or methods that were conducted.

(C) The methods that will be used for determining continuing compliance, including a description of monitoring and reporting requirements and test methods.

(D) The type and quantity of air pollutants emitted by the source, reported in units of the standard.

(E) A description of the air pollution control equipment and burners installed as required by this section for each emission point.

(F) A statement by the owner or operator as to whether the source has complied with the relevant standards and other requirements.

(3) The owner or operator must develop and implement a written startup, shutdown, and malfunction plan for NO<sub>x</sub> and SO<sub>2</sub>. The plan must include, at a minimum, procedures for operating and maintaining the source during periods of startup, shutdown, and malfunction and a program of

corrective action for a malfunctioning process and air pollution control and monitoring equipment used to comply with the relevant standard. The plan must ensure that, at all times, the owner or operator operates and maintains each affected source, including associated air pollution control and monitoring equipment, in a manner which satisfies the general duty to minimize or eliminate emissions using good air pollution control practices. The plan must ensure that owners or operators are prepared to correct malfunctions as soon as practicable after their occurrence.

(4) The written reports of the results of each performance evaluation and QA/QC check in accordance with and as required in paragraph (l)(4)(v) of this section.

(5) *Compliance reports.* The owner or operator of each BART affected unit must submit semiannual compliance reports. The semiannual compliance reports must be submitted in accordance with paragraphs (n)(5)(i) through (iv) of this section, unless the Regional Administrator has approved a different schedule.

(i) The first compliance report must cover the period beginning on the compliance date that is specified for the affected source through June 30 or December 31, whichever date comes first after the compliance date that is specified for the affected source.

(ii) The first compliance report must be postmarked no later than 30 calendar days after the reporting period covered by that report (July 30 or January 30), whichever comes first.

(iii) Each subsequent compliance report must cover the semiannual reporting period from January 1 through June 30 or the semiannual reporting period from July 1 through December 31.

(iv) Each subsequent compliance report must be postmarked no later than 30 calendar days after the reporting period covered by that report (July 30 or January 30).

(6) *Compliance report contents.* Each compliance report must include the information in paragraphs (n)(6)(i) through (vi) of this section.

(i) Company name and address.

(ii) Statement by a responsible official, with the official's name, title, and signature, certifying the truth, accuracy, and completeness of the content of the report.

(iii) Date of report and beginning and ending dates of the reporting period.

(iv) Identification of the process unit, control devices, and CEMS covered by the compliance report.

(v) A record of each period of a startup, shutdown, or malfunction during the reporting period and a description of the actions the owner or operator took to minimize or eliminate emissions arising as a result of the startup, shutdown, or malfunction and whether those actions were or were not consistent with the source's startup, shutdown, and malfunction plan.

(vi) A statement identifying whether there were or were not any deviations from the requirements of this section during the reporting period. If there were deviations from the requirements of this section during the reporting period, then the compliance report must describe in detail the deviations which occurred, the causes of the deviations, actions taken to address the deviations, and procedures put in place to avoid such deviations in the future. If there were no deviations from the requirements of this section during the reporting period, then the compliance report must include a statement that there were no deviations. For purposes of this section, deviations include, but are not limited to, emissions in excess of applicable emission standards established by this section, failure to continuously operate an air pollution control device in accordance with operating requirements designed to assure compliance with emission standards, failure to continuously operate CEMS required by this section, and failure to maintain records or submit reports required by this section.

(7) Each owner or operator of a CEMS required by this section must submit quarterly excess emissions and monitoring system performance reports to the Regional Administrator for each pollutant monitored for each BART affected unit monitored. All reports must be postmarked by the 30th day following the end of each 3-month period of a calendar year (January–March, April–June, July–September, October–December) and must include, at a minimum, the requirements of paragraphs (n)(7)(i) through (xv) of this section.

(i) Company name and address.

(ii) Identification and description of the process unit being monitored.

(iii) The dates covered by the reporting period.

(iv) Total source operating hours for the reporting period.

(v) Monitor manufacturer, monitor model number, and monitor serial number.

(vi) Pollutant monitored.

(vii) Emission limitation for the monitored pollutant.

(viii) Date of latest CEMS certification or audit.

(ix) A description of any changes in continuous monitoring systems, processes, or controls since the last reporting period.

(x) A table summarizing the total duration of excess emissions, as defined in paragraphs (n)(7)(x)(A) through (B) of this section, for the reporting period broken down by the cause of those excess emissions (startup/shutdown, control equipment problems, process problems, other known causes, unknown causes), and the total percent of excess emissions (for all causes) for the reporting period calculated as described in paragraph (n)(7)(x)(C) of this section.

(A) For purposes of this section, an excess emission is defined as any 30-day or 720-hour rolling average period, including periods of startup, shutdown, and malfunction, during which the 30-day or 720-hour (as appropriate) rolling average emissions of either regulated pollutant (SO<sub>2</sub> and NO<sub>x</sub>), as measured by a CEMS, exceeds the applicable emission standards in this section.

(B)(1) For purposes of this section, if a facility calculates a 30-day rolling average emission rate in accordance with this section which exceeds the applicable emission standards of this section, then it will be considered 30 days of excess emissions. If the following 30-day rolling average emission rate is calculated and found to exceed the applicable emission standards of this section as well, then it will add one more day to the total days of excess emissions (*i.e.* 31 days). Similarly, if an excess emission is calculated for a 30-day rolling average period and no additional excess emissions are calculated until 15 days after the first, then that new excess emission will add 15 days to the total days of excess emissions (*i.e.* 30 + 15 = 45). For purposes of this section, if an excess emission is calculated for any period of time within a reporting period, there will be no fewer than 30 days of excess emissions but there should be no more than 121 days of excess emissions for a reporting period.

(2) For purposes of this section, if a facility calculates a 720-hour rolling average emission rate in accordance with this section which exceeds the applicable emission standards of this section, then it will be considered 30 days of excess emissions. If the 24th following 720-hour rolling average emission rate is calculated and found to exceed the applicable emission standards of the rule as well, then it will add one more day to the total days of excess emissions (*i.e.* 31 days). Similarly, if an excess emission is calculated for a 720-hour rolling average

period and no additional excess emissions are calculated until 360 hours after the first, then that new excess emission will add 15 days to the total days of excess emissions (*i.e.* 30+15 = 45). For purposes of this section, if an excess emission is calculated for any period of time with a reporting period, there will be no fewer than 30 days of excess emissions but there should be no more than 121 days of excess emissions for a reporting period.

(C) For purposes of this section, the total percent of excess emissions will be determined by summing all periods of excess emissions (in days) for the reporting period, dividing that number by the total BART affected unit operating days for the reporting period, and then multiplying by 100 to get the total percent of excess emissions for the reporting period. An operating day, as defined previously, is any day during which fuel is fired in the BART affected unit for any period of time. Because of the possible overlap of 30-day rolling average excess emissions across quarters, there are some situations where the total percent of excess emissions could exceed 100 percent. This extreme situation would only result from serious excess emissions problems where excess emissions occur for nearly every day during a reporting period.

(xi) A table summarizing the total duration of monitor downtime, as defined in paragraph (n)(7)(xi)(A) of this section, for the reporting period broken down by the cause of the monitor downtime (monitor equipment malfunctions, non-monitor equipment malfunctions, quality assurance calibration, other known causes, unknown causes), and the total percent of monitor downtime (for all causes) for the reporting period calculated as described in paragraph (n)(7)(xi)(B) of this section.

(A) For purposes of this section, monitor downtime is defined as any period of time (in hours) during which the required monitoring system was not measuring emissions from the BART affected unit. This includes any period of CEMS QA/QC, daily zero and span checks, and similar activities.

(B) For purposes of this section, the total percent of monitor downtime will be determined by summing all periods of monitor downtime (in hours) for the reporting period, dividing that number by the total number of BART affected unit operating hours for the reporting period, and then multiplying by 100 to get the total percent of excess emissions for the reporting period.

(xii) A table which identifies each period of excess emissions for the

reporting period and includes, at a minimum, the information in paragraphs (n)(7)(xii)(A) through (F) of this section.

(A) The date of each excess emission.

(B) The beginning and end time of each excess emission.

(C) The pollutant for which an excess emission occurred.

(D) The magnitude of the excess emission.

(E) The cause of the excess emission.

(F) The corrective action taken or preventative measures adopted to minimize or eliminate the excess emissions and prevent such excess emission from occurring again.

(xiii) A table which identifies each period of monitor downtime for the reporting period and includes, at a minimum, the information in paragraphs (n)(7)(xiii)(A) through (D) of this section.

(A) The date of each period of monitor downtime.

(B) The beginning and end time of each period of monitor downtime.

(C) The cause of the period of monitor downtime.

(D) The corrective action taken or preventative measures adopted for system repairs or adjustments to minimize or eliminate monitor downtime and prevent such downtime from occurring again.

(xiv) If there were no periods of excess emissions during the reporting period, then the excess emission report must include a statement which says there were no periods of excess emissions during this reporting period.

(xv) If there were no periods of monitor downtime, except for daily zero and span checks, during the reporting period, then the excess emission report must include a statement which says there were no periods of monitor downtime during this reporting period except for the daily zero and span checks.

(8) The owner or operator of each CEMS required by this section must develop and submit for review and approval by the Regional Administrator a site specific monitoring plan. The purpose of this monitoring plan is to establish procedures and practices which will be implemented by the owner or operator in its effort to comply with the monitoring, recordkeeping, and reporting requirements of this section. The monitoring plan must include, at a minimum, the information in paragraphs (n)(8)(i) through (x) of this section.

(i) Site specific information including the company name, address, and contact information.

(ii) The objectives of the monitoring program implemented and information

describing how those objectives will be met.

(iii) Information on any emission factors used in conjunction with the CEMS required by this section to calculate emission rates and a description of how those emission factors were determined.

(iv) A description of methods to be used to calculate emission rates when CEMS data are not available due to downtime associated with QA/QC events.

(v) A description of the QA/QC program to be implemented by the owner or operator of CEMS required by this section. This can be the QA/QC program developed in accordance with 40 CFR part 60, appendix F, Procedure 1, Section 3.

(vi) A list of spare parts for CEMS maintained on site for system maintenance and repairs.

(vii) A description of the procedures to be used to calculate 30-day rolling averages and 720-hour rolling averages and example calculations which show the algorithms used by the CEMS to calculate 30-day rolling averages and 720-hour rolling averages.

(viii) A sample of the document to be used for the quarterly excess emission reports required by this section.

(ix) A description of the procedures to be implemented to investigate root causes of excess emissions and monitor downtime and the proposed corrective actions to address potential root causes of excess emissions and monitor downtime.

(x) A description of the sampling and calculation methodology for determining the percent sulfur by weight as a monthly block average for coal used during that month.

(p) *Equations for establishing the upper predictive limit*—(1) *Equation for normal distribution and statistically independent data.*

$$UPL = \bar{x} + t_{[(n-1),(0.95)]} \sqrt{s^2 \left( \frac{1}{n} + \frac{1}{m} \right)}$$

Where:

$\bar{x}$  = average or mean of hourly test run data;  
 $t_{[(n-1),(0.95)]}$  = t score, the one-tailed t value of the Student's t distribution for a specific degree of freedom (n - 1) and a confidence level (0.95; 0.99 for Tilden SO<sub>2</sub>)

$s^2$  = variance of the hourly data set;

$n$  = number of values (e.g. 5,760 if 8 months of valid lbs NO<sub>x</sub>/MMBTU hourly values)

$m$  = number of values used to calculate the test average (m = 720 as per averaging time)

(i) To determine if statistically independent, use the Rank von Neumann Test on p. 137 of data Quality

Assessment: Statistical Methods for Practitioners EPA QA/G-9S.

(ii) Alternative to Rank von Neumann test to determine if data are dependent, data are dependent if t test value is greater than t critical value, where:

$$t \text{ test} = \frac{\rho}{\sqrt{\frac{1-\rho^2}{n-2}}}$$

$\rho$  = correlation between data points  
*t critical* =  $t_{[(n-2),(0.95)]}$  = t score, the two-tailed t value of the Student's t distribution for a specific degree of freedom (n - 2) and a confidence level (0.95)

(iii) The Anderson-Darling normality test is used to establish whether the data are normally distributed. That is, a distribution is considered to be normally distributed when  $p > 0.05$ .

(2) *Non-parametric equation for data not normally distributed and normally distributed but not statistically independent.*

$$m = (n + 1) * \alpha$$

$m$  = the rank of the ordered data point, when data are sorted smallest to largest. The data points are 720-hour averages for establishing NO<sub>x</sub> limits.

$n$  = number of data points (e.g., 5040 720-hourly averages for eight months of valid NO<sub>x</sub> lbs/MMBTU values)

$\alpha$  = 0.95, to reflect the 95th percentile

If  $m$  is a whole number, then the limit, UPL, shall be computed as:

$$UPL = X_m$$

Where:

$X_m$  = value of the  $m^{th}$  data point in terms of lbs SO<sub>2</sub>/hr or lbs NO<sub>x</sub>/MMBTU, when the data are sorted smallest to largest.

If  $m$  is not a whole number, the limit shall be computed by linear interpolation according to the following equation.

$$UPL = X_m = X_{m_i}; m_d = X_{m_i} + 0. m_d (X_{m_i+1} - X_{m_i})$$

Where:

$m_i$  = the integer portion of  $m$ , i.e.,  $m$  truncated at zero decimal places, and  
 $m_d$  = the decimal portion of  $m$

■ 3. Section 52.1235 is amended by revising paragraphs (b)(1)(ii), (b)(1)(iv), (b)(1)(v), (b)(2)(iv), (c), (d), and (e) and by adding paragraph (f) to read as follows:

**§ 52.1235 Regional haze.**

\* \* \* \* \*

(b)

(1) \* \* \*

(ii) *Hibbing Taconite Company*—(A) *Hibbing Line 1.* (1) An emission limit of 1.2 lbs NO<sub>x</sub>/MMBTU, based on a 30-day rolling average, shall apply to Hibbing Line 1 when burning natural gas. This

emission limit will become enforceable 37 months after May 12, 2016 and only after EPA's confirmation or modification of the emission limit in accordance with the procedures set forth in paragraphs (b)(1)(ii)(A)(2) through (7) of this section.

(2) Compliance with this emission limit will be demonstrated with data collected by a continuous emissions monitoring system (CEMS) for NO<sub>x</sub>. The owner or operator of Hibbing Line 1 must install a CEMS for NO<sub>x</sub> and SO<sub>2</sub> within six months from May 12, 2016. The owner or operator must start collecting CEMS data and submit the data to EPA no later than 30 days from the end of each calendar quarter after that installation deadline. Any remaining data through the end of the 34th month from May 12, 2016, that does not fall within a calendar quarter, must be submitted to EPA no later than 30 days from the end of the 34th month. Although CEMS data must continue to be collected, it does not need to be submitted to EPA starting 34 months after May 12, 2016.

(3) No later than 24 months after May 12, 2016 the owner or operator must submit to EPA a report, including any final report(s) completed by the selected NO<sub>x</sub> reduction technology supplier and furnace retrofit engineer, containing a detailed engineering analysis and modeling of the NO<sub>x</sub> reduction control technology being installed on Hibbing Line 1. The NO<sub>x</sub> reduction control technology must be designed to meet an emission limit of 1.2 lbs NO<sub>x</sub>/MMBTU. This report must include a list of all process and control technology variables that can reasonably be expected to have an impact on NO<sub>x</sub> emissions control technology performance, as well as a description of how these variables can be adjusted to reduce NO<sub>x</sub> emissions to meet the NO<sub>x</sub> design emission limit.

(4) The NO<sub>x</sub> reduction control technology shall be installed on Hibbing Line 1 furnace no later than 26 months after May 12, 2016.

(5) Commencing on the earlier of: Six months from the installation of the NO<sub>x</sub> reduction control technology; or 26 months from May 12, 2016, the owner or operator must provide to EPA the results from pellet quality analyses. The owner or operator shall provide the results from pellet quality analyses no later than 30 days from the end of each calendar quarter up until 34 months after May 12, 2016. Any remaining results through the end of the 34th month from May 12, 2016, that do not fall within a calendar quarter, must be submitted to EPA no later than 30 days from the end of the 34th month. The

pellet quality analyses shall include results for the following factors: Compression, reducibility, before tumble, after tumble, low temperature disintegration, and swelling. For each of the pellet quality analysis factors, the owner or operator must explain the pellet quality analysis factor, as well as the defined acceptable range for each factor using the applicable product quality standards based upon customers' pellet specifications that are contained in Hibbing's ISO 9001 quality management system. The owner or operator shall provide pellet quality analysis testing results that state the date and time of the analysis and, in order to define the time period when pellets were produced outside of the defined acceptable range for the pellet quality factors listed, provide copies of the production logs that document the starting and ending times for such periods. The owner or operator shall provide an explanation of causes for pellet samples that fail to meet the acceptable range for any pellet quality analysis factor. Pellet quality information and data may be submitted to EPA as Confidential Business Information.

(6) No later than 34 months after May 12, 2016, the owner or operator may submit to EPA a report to either confirm or modify the NO<sub>x</sub> limits for Hibbing Line 1 furnace within the upper and lower bounds described below. EPA will review the report and either confirm or modify the NO<sub>x</sub> limits. If the CEMS data collected during operating periods between months 26 and 34 that both meet pellet quality specifications and proper furnace/burner operation is normally distributed, the limit adjustment determination shall be based on the appropriate (depending upon whether data are statistically independent or dependent) 95% upper predictive limit (UPL) equations in paragraph (f) of this section. If the CEMS data collected during operating periods between months 26 and 34 that both meet pellet quality specifications and proper furnace/burner operation are not normally distributed, the limit adjustment determination shall be based on the non-parametric equation provided in paragraph (f) of this section. The data set for the determination shall exclude periods when pellet quality did not fall within the defined acceptable ranges of the pellet quality factors identified pursuant to paragraph (b)(1)(ii)(E) of this section and for any subsequent period when production has been reduced in response to pellet quality concerns consistent with Hibbing's ISO 9001 operating standards.

Any excluded period will commence at the time documented on the production log demonstrating that pellet quality did not fall within the defined acceptable range and shall end when pellet quality within the defined acceptable range has been re-established at planned production levels, which will be presumed to be the level that existed immediately prior to the reduction in production due to pellet quality concerns. EPA may also exclude data where operations are inconsistent with the reported design parameters of the NO<sub>x</sub> reduction control technology installed.

(7) EPA will take final agency action by publishing its final confirmation or modification of the NO<sub>x</sub> limit in the **Federal Register** no later than 37 months after May 12, 2016. The confirmed or modified NO<sub>x</sub> limit for Hibbing Line 1 when burning only natural gas may be no lower than 1.2 lbs NO<sub>x</sub>/MMBTU, based on a 30-day rolling average, and may not exceed 1.8 lbs NO<sub>x</sub>/MMBTU, based on a 30-day rolling average.

(B) *Hibbing Line 2.* (1) An emission limit of 1.2 lbs NO<sub>x</sub>/MMBTU, based on a 30-day rolling average, shall apply to Hibbing Line 2 when burning natural gas. This emission limit will become enforceable 55 months after May 12, 2016 and only after EPA's confirmation or modification of the emission limit in accordance with the procedures set forth in paragraphs (b)(1)(ii)(B)(2) through (7) of this section.

(2) Compliance with this emission limit will be demonstrated with data collected by a continuous emissions monitoring system (CEMS) for NO<sub>x</sub>. The owner or operator of Hibbing Line 2 must install a CEMS for NO<sub>x</sub> and SO<sub>2</sub> within six months from May 12, 2016. The owner or operator must start collecting CEMS data and submit the data to EPA no later than 30 days from the end of each calendar quarter after that installation deadline. Any remaining data through the end of the 52nd month from May 12, 2016, that does not fall within a calendar quarter, must be submitted to EPA no later than 30 days from the end of the 52nd month. Although CEMS data must continue to be collected, it does not need to be submitted to EPA starting 52 months after May 12, 2016.

(3) No later than 42 months after May 12, 2016 the owner or operator must submit to EPA a report, including any final report(s) completed by the selected NO<sub>x</sub> reduction technology supplier and furnace retrofit engineer, containing a detailed engineering analysis and modeling of the NO<sub>x</sub> reduction control technology being installed on Hibbing

Line 2. The NO<sub>x</sub> reduction control technology must be designed to meet an emission limit of 1.2 lbs NO<sub>x</sub>/MMBTU. This report must include a list of all process and control technology variables that can reasonably be expected to have an impact on NO<sub>x</sub> emissions control technology performance, as well as a description of how these variables can be adjusted to reduce NO<sub>x</sub> emissions to meet the NO<sub>x</sub> design emission limit.

(4) The NO<sub>x</sub> reduction control technology shall be installed on Hibbing Line 2 furnace no later than 44 months after May 12, 2016.

(5) Commencing on the earlier of: Six months from the installation of the NO<sub>x</sub> reduction control technology; or 44 months from May 12, 2016, the owner or operator must provide to EPA the results from pellet quality analyses. The owner or operator shall provide the results from pellet quality analyses no later than 30 days from the end of each calendar quarter up until 52 months after May 12, 2016. Any remaining results through the end of the 52nd month from May 12, 2016, that do not fall within a calendar quarter, must be submitted to EPA no later than 30 days from the end of the 52nd month. The pellet quality analyses shall include results for the following factors: Compression, reducibility, before tumble, after tumble, low temperature disintegration, and swelling. For each of the pellet quality analysis factors, the owner or operator must explain the pellet quality analysis factor, as well as the defined acceptable range for each factor using the applicable product quality standards based upon customers' pellet specifications that are contained in Hibbing's ISO 9001 quality management system. The owner or operator shall provide pellet quality analysis testing results that state the date and time of the analysis and, in order to define the time period when pellets were produced outside of the defined acceptable range for the pellet quality factors listed, provide copies of the production logs that document the starting and ending times for such periods. The owner or operator shall provide an explanation of causes for pellet samples that fail to meet the acceptable range for any pellet quality analysis factor. Pellet quality information and data may be submitted to EPA as Confidential Business Information.

(6) No later than 52 months after May 12, 2016, the owner or operator may submit to EPA a report to either confirm or modify the NO<sub>x</sub> limits for Hibbing Line 2 furnace within the upper and lower bounds described below. EPA

will review the report and either confirm or modify the NO<sub>x</sub> limits. If the CEMS data collected during operating periods between months 44 and 52 that both meet pellet quality specifications and proper furnace/burner operation is normally distributed, the limit adjustment determination shall be based on the appropriate (depending upon whether data are statistically independent or dependent) 95% upper predictive limit (UPL) equations in paragraph (f) of this section. If the CEMS data collected during operating periods between months 44 and 52 that both meet pellet quality specifications and proper furnace/burner operation are not normally distributed, the limit adjustment determination shall be based on the non-parametric equation provided in paragraph (f) of this section. The data set for the determination shall exclude periods when pellet quality did not fall within the defined acceptable ranges of the pellet quality factors identified pursuant to paragraph (b)(1)(ii)(E) of this section and for any subsequent period when production has been reduced in response to pellet quality concerns consistent with Hibbing's ISO 9001 operating standards. Any excluded period will commence at the time documented on the production log demonstrating that pellet quality did not fall within the defined acceptable range and shall end when pellet quality within the defined acceptable range has been re-established at planned production levels, which will be presumed to be the level that existed immediately prior to the reduction in production due to pellet quality concerns. EPA may also exclude data where operations are inconsistent with the reported design parameters of the NO<sub>x</sub> reduction control technology installed.

(7) EPA will take final agency action by publishing its final confirmation or modification of the NO<sub>x</sub> limit in the **Federal Register** no later than 55 months after May 12, 2016. The confirmed or modified NO<sub>x</sub> limit for Hibbing Line 2 when burning only natural gas may be no lower than 1.2 lbs NO<sub>x</sub>/MMBTU, based on a 30-day rolling average, and may not exceed 1.8 lbs NO<sub>x</sub>/MMBTU, based on a 30-day rolling average.

(C) *Hibbing Line 3.* (1) An emission limit of 1.2 lbs NO<sub>x</sub>/MMBTU, based on a 30-day rolling average, shall apply to Hibbing Line 3 when burning natural gas. This emission limit will become enforceable 60 months after May 12, 2016 and only after EPA's confirmation or modification of the emission limit in accordance with the procedures set

forth in paragraphs (b)(1)(ii)(C)(2) through (7) of this section.

(2) Compliance with this emission limit will be demonstrated with data collected by a continuous emissions monitoring system (CEMS) for NO<sub>x</sub>. The owner or operator of Hibbing Line 3 must install a CEMS for NO<sub>x</sub> and SO<sub>2</sub> within six months from May 12, 2016. The owner or operator must start collecting CEMS data and submit the data to EPA no later than 30 days from the end of each calendar quarter after that installation deadline. Any remaining data through the end of the 57th month from May 12, 2016, that does not fall within a calendar quarter, must be submitted to EPA no later than 30 days from the end of the 57th month. Although CEMS data must continue to be collected, it does not need to be submitted to EPA starting 57 months after May 12, 2016.

(3) No later than 48 months after May 12, 2016 the owner or operator must submit to EPA a report, including any final report(s) completed by the selected NO<sub>x</sub> reduction technology supplier and furnace retrofit engineer, containing a detailed engineering analysis and modeling of the NO<sub>x</sub> reduction control technology being installed on Hibbing Line 3. The NO<sub>x</sub> reduction control technology must be designed to meet an emission limit of 1.2 lbs NO<sub>x</sub>/MMBTU. This report must include a list of all process and control technology variables that can reasonably be expected to have an impact on NO<sub>x</sub> emissions control technology performance, as well as a description of how these variables can be adjusted to reduce NO<sub>x</sub> emissions to meet the NO<sub>x</sub> design emission limit.

(4) The NO<sub>x</sub> reduction control technology shall be installed on Hibbing Line 3 furnace no later than 50 months after May 12, 2016.

(5) Commencing on the earlier of: Six months from the installation of the NO<sub>x</sub> reduction control technology; or 50 months from May 12, 2016, the owner or operator must provide to EPA the results from pellet quality analyses. The owner or operator shall provide the results from pellet quality analyses no later than 30 days from the end of each calendar quarter up until 57 months after May 12, 2016. Any remaining results through the end of the 57th month from May 12, 2016, that do not fall within a calendar quarter, must be submitted to EPA no later than 30 days from the end of the 57th month. The pellet quality analyses shall include results for the following factors: Compression, reducibility, before tumble, after tumble, low temperature disintegration, and swelling. For each of

the pellet quality analysis factors, the owner or operator must explain the pellet quality analysis factor, as well as the defined acceptable range for each factor using the applicable product quality standards based upon customers' pellet specifications that are contained in Hibbing's ISO 9001 quality management system. The owner or operator shall provide pellet quality analysis testing results that state the date and time of the analysis and, in order to define the time period when pellets were produced outside of the defined acceptable range for the pellet quality factors listed, provide copies of the production logs that document the starting and ending times for such periods. The owner or operator shall provide an explanation of causes for pellet samples that fail to meet the acceptable range for any pellet quality analysis factor. Pellet quality information and data may be submitted to EPA as Confidential Business Information.

(6) No later than 57 months after May 12, 2016, the owner or operator may submit to EPA a report to either confirm or modify the NO<sub>x</sub> limits for Hibbing Line 3 furnace within the upper and lower bounds described below. EPA will review the report and either confirm or modify the NO<sub>x</sub> limits. If the CEMS data collected during operating periods between months 50 and 57 that both meet pellet quality specifications and proper furnace/burner operation is normally distributed, the limit adjustment determination shall be based on the appropriate (depending upon whether data are statistically independent or dependent) 95% upper predictive limit (UPL) equations in paragraph (f) of this section. If the CEMS data collected during operating periods between months 50 and 57 that both meet pellet quality specifications and proper furnace/burner operation are not normally distributed, the limit adjustment determination shall be based on the non-parametric equation provided in paragraph (f) of this section. The data set for the determination shall exclude periods when pellet quality did not fall within the defined acceptable ranges of the pellet quality factors identified pursuant to paragraph (b)(1)(ii)(E) of this section and for any subsequent period when production has been reduced in response to pellet quality concerns consistent with Hibbing's ISO 9001 operating standards. Any excluded period will commence at the time documented on the production log demonstrating that pellet quality did not fall within the defined acceptable range and shall end when pellet quality

within the defined acceptable range has been re-established at planned production levels, which will be presumed to be the level that existed immediately prior to the reduction in production due to pellet quality concerns. EPA may also exclude data where operations are inconsistent with the reported design parameters of the NO<sub>x</sub> reduction control technology installed.

(7) EPA will take final agency action by publishing its final confirmation or modification of the NO<sub>x</sub> limit in the **Federal Register** no later than 60 months after May 12, 2016. The confirmed or modified NO<sub>x</sub> limit for Hibbing Line 3 when burning only natural gas may be no lower than 1.2 lbs NO<sub>x</sub>/MMBTU, based on a 30-day rolling average, and may not exceed 1.8 lbs NO<sub>x</sub>/MMBTU, based on a 30-day rolling average.

\* \* \* \* \*

(iv) *United Taconite*—(A) *United Taconite Line 1*. (1) An emission limit of 2.8 lbs NO<sub>x</sub>/MMBTU, based on a 720-hour rolling average, shall apply to United Taconite Grate Kiln Line 1 when burning natural gas, and an emission limit of 1.5 lbs NO<sub>x</sub>/MMBTU, based on a 720-hour rolling average, shall apply to United Taconite Grate Kiln Line 1 when burning coal or a mixture of coal and natural gas. These emission limits will become enforceable 37 months after May 12, 2016 and only after EPA's confirmation or modification of the emission limit in accordance with the procedures set forth in paragraphs (b)(1)(iv)(A)(2) through (8) of this section.

(2) Compliance with these emission limits shall be demonstrated with data collected by a continuous emissions monitoring system (CEMS) for NO<sub>x</sub>. The owner or operator must start collecting CEMS data for NO<sub>x</sub> on May 12, 2016 and submit the data to EPA no later than 30 days from the end of each calendar quarter. Any remaining data through the end of the 34th month from May 12, 2016, that does not fall within a calendar quarter, must be submitted to EPA no later than 30 days from the end of the 34th month. Although CEMS data must continue to be collected, it does not need to be submitted to EPA starting 34 months after May 12, 2016.

(3) No later than 24 months from May 12, 2016, the owner or operator must submit to EPA a report, including any final report(s) completed by the selected NO<sub>x</sub> reduction technology supplier and furnace retrofit engineer, containing a detailed engineering analysis and modeling of the NO<sub>x</sub> reduction control technology being installed on United

Taconite Grate Kiln Line 1. This report must include a list of all variables that can reasonably be expected to have an impact on NO<sub>x</sub> emission control technology performance, as well as a description of how these variables can be adjusted to reduce NO<sub>x</sub> emissions to meet the NO<sub>x</sub> design emission limit. This NO<sub>x</sub> reduction control technology must be designed to meet emission limits of 2.8 lbs NO<sub>x</sub>/MMBTU when burning natural gas and 1.5 lbs NO<sub>x</sub>/MMBTU when burning coal or a mixture of coal and natural gas.

(4) The NO<sub>x</sub> reduction control technology shall be installed on United Taconite Grate Kiln Line 1 furnace no later than 26 months from May 12, 2016.

(5) Commencing on the earlier of: Six months from the installation of the NO<sub>x</sub> reduction control technology or 26 months from May 12, 2016, the owner or operator must provide to EPA the results from pellet quality analyses. The owner or operator shall provide the results from pellet quality analyses no later than 30 days from the end of each calendar quarter up until 34 months after May 12, 2016. Any remaining results through the end of the 34th month, that do not fall within a calendar quarter, must be submitted to EPA no later than 30 days from the end of the 34th month. The pellet quality analyses shall include results for the following factors: Compression, reducibility, before tumble, after tumble, and low temperature disintegration. For each of the pellet quality analysis factors, the owner or operator must explain the pellet quality analysis factor, as well as the defined acceptable range for each factor using the applicable product quality standards based upon customers' pellet specifications that are contained in United Taconite's ISO 9001 quality management system. The owner or operator shall provide pellet quality analysis testing results that state the date and time of the analysis and, in order to define the time period when pellets were produced outside of the defined acceptable range for the pellet quality factors listed, provide copies of the production logs that document the starting and ending times for such periods. The owner or operator shall provide an explanation of causes for pellet samples that fail to meet the acceptable range for any pellet quality analysis factor. Pellet quality information and data may be submitted to EPA as Confidential Business Information.

(6) No later than 34 months after May 12, 2016, the owner or operator may submit to EPA a report to either confirm or modify the NO<sub>x</sub> limits for United Taconite Grate Kiln Line 1 within the

upper and lower bounds described below. EPA will review the report and either confirm or modify the NO<sub>x</sub> limits. If the CEMS data collected during operating periods between months 26 and 34 that both meet pellet quality specifications and proper furnace/burner operation is normally distributed, the limit adjustment determination shall be based on the appropriate (depending upon whether data are statistically independent or dependent) 95% upper predictive limit (UPL) equations in paragraph (f) of this section. If the CEMS data collected during operating periods between months 26 and 34 that both meet pellet quality specifications and proper furnace/burner operation are not normally distributed, the limit adjustment determination shall be based on the non-parametric equation provided in paragraph (f) of this section. The data set for the determination shall exclude periods when pellet quality did not fall within the defined acceptable ranges of the pellet quality factors identified pursuant to paragraph (b)(1)(iv)(A)(5) of this section and for any subsequent period when production had been reduced in response to pellet quality concerns consistent with United Taconite's ISO 9001 operating standards. Any excluded period will commence at the time documented on the production log demonstrating pellet quality did not fall within the defined acceptable range, and shall end when pellet quality within the defined acceptable range has been re-established at planned production levels, which will be presumed to be the level that existed immediately prior to the reduction in production due to pellet quality concerns. EPA may also exclude data where operations are inconsistent with the reported design parameters of the NO<sub>x</sub> reduction control technology that were installed.

(7) EPA will take final agency action by publishing its final confirmation or modification of the NO<sub>x</sub> limits in the **Federal Register** no later than 37 months after May 12, 2016. The confirmed or modified NO<sub>x</sub> limit for United Taconite Grate Kiln Line 1 when burning only natural gas may be no lower than 2.8 lbs NO<sub>x</sub>/MMBTU, based on a 720-hour rolling average, and may not exceed 3.0 lbs NO<sub>x</sub>/MMBTU, based on a 720-hour rolling average. The confirmed or modified NO<sub>x</sub> limit for United Taconite Grate Kiln Line 1 when burning coal or a mixture of coal and natural gas may be no lower than 1.5 lbs NO<sub>x</sub>/MMBTU, based on a 720-hour rolling average, and may not exceed 2.5



lbs NO<sub>x</sub>/MMBTU, based on a 720-hour rolling average.

(8) If the owner or operator submits a report proposing a single NO<sub>x</sub> limit for all fuels, EPA may approve the proposed NO<sub>x</sub> limit for all fuels based on a 30-day rolling average. The confirmed or modified limit will be established and enforceable within 37 months from May 12, 2016.

(B) *United Taconite Line 2.* (1) An emission limit of 2.8 lbs NO<sub>x</sub>/MMBTU, based on a 720-hour rolling average, shall apply to United Taconite Grate Kiln Line 2 when burning natural gas, and an emission limit of 1.5 lbs NO<sub>x</sub>/MMBTU, based on a 720-hour rolling average, shall apply to United Taconite Grate Kiln Line 2 when burning coal or a mixture of coal and natural gas. These emission limits will become enforceable 55 months after May 12, 2016 and only after EPA's confirmation or modification of the emission limit in accordance with the procedures set forth in paragraphs (b)(1)(iv)(B)(2) through (8) of this section.

(2) Compliance with these emission limits shall be demonstrated with data collected by a continuous emissions monitoring system (CEMS) for NO<sub>x</sub>. The owner or operator must start collecting CEMS data for NO<sub>x</sub> on May 12, 2016 and submit the data to EPA no later than 30 days from the end of each calendar quarter. Any remaining data through the end of the 52nd month from May 12, 2016, that does not fall within a calendar quarter, must be submitted to EPA no later than 30 days from the end of the 52nd month. Although CEMS data must continue to be collected, it does not need to be submitted to EPA starting 52 months after May 12, 2016.

(3) No later than 42 months from May 12, 2016, the owner or operator must submit to EPA a report, including any final report(s) completed by the selected NO<sub>x</sub> reduction technology supplier and furnace retrofit engineer, containing a detailed engineering analysis and modeling of the NO<sub>x</sub> reduction control technology being installed on United Taconite Grate Kiln Line 2. This report must include a list of all variables that can reasonably be expected to have an impact on NO<sub>x</sub> emission control technology performance, as well as a description of how these variables can be adjusted to reduce NO<sub>x</sub> emissions to meet the NO<sub>x</sub> design emission limit. This NO<sub>x</sub> reduction control technology must be designed to meet emission limits of 2.8 lbs NO<sub>x</sub>/MMBTU when burning natural gas and 1.5 lbs NO<sub>x</sub>/MMBTU when burning coal or a mixture of coal and natural gas.

(4) The NO<sub>x</sub> reduction control technology shall be installed on United

Taconite Grate Kiln Line 2 furnace no later than 44 months from May 12, 2016.

(5) Commencing on the earlier of: Six months from the installation of the NO<sub>x</sub> reduction control technology or 44 months from May 12, 2016, the owner or operator must provide to EPA the results from pellet quality analyses. The owner or operator shall provide the results from pellet quality analyses no later than 30 days from the end of each calendar quarter up until 52 months after May 12, 2016. Any remaining results through the end of the 52nd month, that do not fall within a calendar quarter, must be submitted to EPA no later than 30 days from the end of the 52nd month. The pellet quality analyses shall include results for the following factors: Compression, reducibility, before tumble, after tumble, and low temperature disintegration. For each of the pellet quality analysis factors, the owner or operator must explain the pellet quality analysis factor, as well as the defined acceptable range for each factor using the applicable product quality standards based upon customers' pellet specifications that are contained in United Taconite's ISO 9001 quality management system. The owner or operator shall provide pellet quality analysis testing results that state the date and time of the analysis and, in order to define the time period when pellets were produced outside of the defined acceptable range for the pellet quality factors listed, provide copies of the production logs that document the starting and ending times for such periods. The owner or operator shall provide an explanation of causes for pellet samples that fail to meet the acceptable range for any pellet quality analysis factor. Pellet quality information and data may be submitted to EPA as Confidential Business Information.

(6) No later than 52 months after May 12, 2016, the owner or operator may submit to EPA a report to either confirm or modify the NO<sub>x</sub> limits for United Taconite Grate Kiln Line 2 within the upper and lower bounds described below. EPA will review the report and either confirm or modify the NO<sub>x</sub> limits. If the CEMS data collected during operating periods between months 44 and 52 that both meet pellet quality specifications and proper furnace/burner operation is normally distributed, the limit adjustment determination shall be based on the appropriate (depending upon whether data are statistically independent or dependent) 95% upper predictive limit (UPL) equations in paragraph (f) of this section. If the CEMS data collected during operating periods between

months 44 and 52 that both meet pellet quality specifications and proper furnace/burner operation are not normally distributed, the limit adjustment determination shall be based on the non-parametric equation provided in paragraph (f) of this section. The data set for the determination shall exclude periods when pellet quality did not fall within the defined acceptable ranges of the pellet quality factors identified pursuant to paragraph (b)(1)(iv)(B)(5) of this section and for any subsequent period when production had been reduced in response to pellet quality concerns consistent with United Taconite's ISO 9001 operating standards. Any excluded period will commence at the time documented on the production log demonstrating pellet quality did not fall within the defined acceptable range, and shall end when pellet quality within the defined acceptable range has been re-established at planned production levels, which will be presumed to be the level that existed immediately prior to the reduction in production due to pellet quality concerns. EPA may also exclude data where operations are inconsistent with the reported design parameters of the NO<sub>x</sub> reduction control technology that were installed.

(7) EPA will take final agency action by publishing its final confirmation or modification of the NO<sub>x</sub> limits in the **Federal Register** no later than 55 months after May 12, 2016. The confirmed or modified NO<sub>x</sub> limit for United Taconite Grate Kiln Line 2 when burning only natural gas may be no lower than 2.8 lbs NO<sub>x</sub>/MMBTU, based on a 720-hour rolling average, and may not exceed 3.0 lbs NO<sub>x</sub>/MMBTU, based on a 720-hour rolling average. The confirmed or modified NO<sub>x</sub> limit for United Taconite Grate Kiln Line 2 when burning coal or a mixture of coal and natural gas may be no lower than 1.5 lbs NO<sub>x</sub>/MMBTU, based on a 720-hour rolling average, and may not exceed 2.5 lbs NO<sub>x</sub>/MMBTU, based on a 720-hour rolling average.

(8) If the owner or operator submits a report proposing a single NO<sub>x</sub> limit for all fuels, EPA may approve the proposed NO<sub>x</sub> limit for all fuels based on a 30-day rolling average. The confirmed or modified limit will be established and enforceable within 55 months from May 12, 2016.

(v) *ArcelorMittal USA—(A)*  
*ArcelorMittal Minorca Mine.* (1) An emission limit of 1.2 lbs NO<sub>x</sub>/MMBTU, based on a 30-day rolling average, shall apply to the ArcelorMittal Minorca Mine indurating furnace when burning natural gas. This emission limit will become enforceable 55 months after

May 12, 2016 and only after EPA's confirmation or modification of the emission limit in accordance with the procedures set forth in paragraphs (b)(1)(v)(A)(2) through (7) of this section.

(2) Compliance with this emission limit will be demonstrated with data collected by a continuous emissions monitoring system (CEMS) for NO<sub>x</sub>. The owner or operator of the ArcelorMittal Minorca Mine indurating furnace must install a CEMS for NO<sub>x</sub> and SO<sub>2</sub> within six months from May 12, 2016. The owner or operator must start collecting CEMS data and submit the data to EPA no later than 30 days from the end of each calendar quarter after that installation deadline. Any remaining data through the end of the 52nd month from May 12, 2016, that does not fall within a calendar quarter, must be submitted to EPA no later than 30 days from the end of the 52nd month. Although CEMS data must continue to be collected, it does not need to be submitted to EPA starting 52 months after May 12, 2016.

(3) No later than 42 months after May 12, 2016 the owner or operator must submit to EPA a report, including any final report(s) completed by the selected NO<sub>x</sub> reduction technology supplier and furnace retrofit engineer, containing a detailed engineering analysis and modeling of the NO<sub>x</sub> reduction control technology being installed on the ArcelorMittal Minorca Mine indurating furnace. The NO<sub>x</sub> reduction control technology must be designed to meet an emission limit of 1.2 lbs NO<sub>x</sub>/MMBTU. This report must include a list of all process and control technology variables that can reasonably be expected to have an impact on NO<sub>x</sub> emissions control technology performance, as well as a description of how these variables can be adjusted to reduce NO<sub>x</sub> emissions to meet the NO<sub>x</sub> design emission limit.

(4) The NO<sub>x</sub> reduction control technology shall be installed on the ArcelorMittal Minorca Mine indurating furnace no later than 44 months after May 12, 2016.

(5) Commencing on the earlier of: Six months from the installation of the NO<sub>x</sub> reduction control technology; or 44 months from May 12, 2016, the owner or operator must provide to EPA the results from pellet quality analyses. The owner or operator shall provide the results from pellet quality analyses no later than 30 days from the end of each calendar quarter up until 52 months after May 12, 2016. Any remaining results through the end of the 52nd month from May 12, 2016, that do not fall within a calendar quarter, must be

submitted to EPA no later than 30 days from the end of the 52nd month. The pellet quality analyses shall include results for the following factors: Compression, reducibility, before tumble, after tumble, low temperature disintegration, and contraction. For each of the pellet quality analysis factors, the owner or operator must explain the pellet quality analysis factor, as well as the defined acceptable range for each factor using the applicable product quality standards based upon customers' pellet specifications that are contained in the ArcelorMittal Minorca Mine's Standard Product Parameters. The owner or operator shall provide pellet quality analysis testing results that state the date and time of the analysis and, in order to define the time period when pellets were produced outside of the defined acceptable range for the pellet quality factors listed, provide copies of production or scale data that document the starting and ending times for such periods. The owner or operator shall provide an explanation of causes for pellet samples that fail to meet the acceptable range for any pellet quality analysis factor. Pellet quality information and data may be submitted to EPA as Confidential Business Information.

(6) No later than 52 months after May 12, 2016, the owner or operator may submit to EPA a report to either confirm or modify the NO<sub>x</sub> limits for the ArcelorMittal Minorca Mine indurating furnace within the upper and lower bounds described below. EPA will review the report and either confirm or modify the NO<sub>x</sub> limits. If the CEMS data collected during operating periods between months 44 and 52 that both meet pellet quality specifications and proper furnace/burner operation is normally distributed, the limit adjustment determination shall be based on the appropriate (depending upon whether data are statistically independent or dependent) 95% upper predictive limit (UPL) equations in paragraph (f) of this section. If the CEMS data collected during operating periods between months 44 and 52 that both meet pellet quality specifications and proper furnace/burner operation are not normally distributed, the limit adjustment determination shall be based on the non-parametric equation provided in paragraph (f) of this section. The data set for the determination shall exclude periods when pellet quality did not fall within the defined acceptable ranges of the pellet quality factors identified pursuant to paragraph (b)(1)(v)(A)(5) of this section and for any subsequent period when production has

been reduced in response to pellet quality concerns consistent with the ArcelorMittal Minorca Mine's Standard Product Parameters. Any excluded period will commence at the time documented in related quality reports demonstrating that pellet quality did not fall within the defined acceptable range and shall end when pellet quality within the defined acceptable range has been re-established at planned production levels, which will be presumed to be the level that existed immediately prior to the reduction in production due to pellet quality concerns. EPA may also exclude data where operations are inconsistent with the reported design parameters of the NO<sub>x</sub> reduction control technology installed.

(7) EPA will take final agency action by publishing its final confirmation or modification of the NO<sub>x</sub> limit in the **Federal Register** no later than 55 months after May 12, 2016. The confirmed or modified NO<sub>x</sub> limit for the ArcelorMittal Minorca Mine indurating furnace when burning only natural gas may be no lower than 1.2 lbs NO<sub>x</sub>/MMBTU, based on a 30-day rolling average, and may not exceed 1.8 lbs NO<sub>x</sub>/MMBTU, based on a 30-day rolling average.

(B) [Reserved]

\* \* \* \* \*

(2) \* \* \*

(iv) United Taconite: An aggregate emission limit of 529.0 lbs SO<sub>2</sub>/hr, based on a 30-day rolling average, shall apply to the Line 1 pellet furnace (EU040) and Line 2 pellet furnace (EU042) beginning six months after May 12, 2016. Compliance with this aggregate emission limit shall be demonstrated with data collected by a continuous emissions monitoring system (CEMS) for SO<sub>2</sub>. The owner or operator must start collecting CEMS data for SO<sub>2</sub> beginning six months after May 12, 2016 and submit the data to EPA no later than 30 days from the end of each calendar quarter. Beginning six months after May 12, 2016, any coal burned on UTAC Grate Kiln Line 1 or Line 2 shall have no more than 1.5 percent sulfur by weight based on a monthly block average. The sampling and calculation methodology for determining the sulfur content of coal must be described in the monitoring plan required for this furnace.

\* \* \* \* \*

(c) *Testing and monitoring.* (1) The owner or operator of the respective facility shall install, certify, calibrate, maintain and operate continuous emissions monitoring systems (CEMS) for NO<sub>x</sub> on United States Steel

Corporation, Keetac unit EU030; Hibbing Taconite Company units EU020, EU021, and EU022; United States Steel Corporation, Minntac units EU225, EU261, EU282, EU315, and EU334; United Taconite units EU040 and EU042; ArcelorMittal Minorca Mine unit EU026; and Northshore Mining Company-Silver Bay units Furnace 11 (EU100/EU104) and Furnace 12 (EU110/EU114). Compliance with the emission limits for NO<sub>x</sub> shall be determined using data from the CEMS.

(2) The owner or operator shall install, certify, calibrate, maintain, and operate CEMS for SO<sub>2</sub> on United States Steel Corporation, Keetac unit EU030; Hibbing Taconite Company units EU020, EU021, and EU022; United States Steel Corporation, Minntac units EU225, EU261, EU282, EU315, and EU334; United Taconite units EU040 and EU042; ArcelorMittal Minorca Mine unit EU026; and Northshore Mining Company-Silver Bay units Furnace 11 (EU100/EU104) and Furnace 12 (EU110/EU114).

(3) The owner or operator shall install, certify, calibrate, maintain, and operate one or more continuous diluent monitor(s) (O<sub>2</sub> or CO<sub>2</sub>) and continuous flow rate monitor(s) on the BART affected units to allow conversion of the NO<sub>x</sub> and SO<sub>2</sub> concentrations to units of the standard (lbs/MMBTU and lbs/hr, respectively) unless a demonstration is made that a diluent monitor and continuous flow rate monitor are not needed for the owner or operator to demonstrate compliance with applicable emission limits in units of the standards.

(4) For purposes of this section, all CEMS required by this section must meet the requirements of paragraphs (c)(4)(i) through (xiv) of this section.

(i) All CEMS must be installed, certified, calibrated, maintained, and operated in accordance with 40 CFR part 60, appendix B, Performance Specification 2 (PS-2) and appendix F, Procedure 1.

(ii) CEMS must be installed and operational as follows:

(A) All CEMS associated with monitoring NO<sub>x</sub> (including the NO<sub>x</sub> monitor and necessary diluent and flow rate monitors) at the following facilities: U.S. Steel Keetac, U.S. Steel Minntac, and Northshore Mining Company-Silver Bay, must be installed and operational no later than the unit specific compliance dates for the emission limits identified at paragraphs (b)(1)(i), (iii) and (vi) of this section, respectively.

(B) All CEMS associated with monitoring NO<sub>x</sub> (including the NO<sub>x</sub> monitor and necessary diluent and flow rate monitors) at the following facilities:

Hibbing Taconite Company, United Taconite, and ArcelorMittal Minorca Mine, must be installed and operational no later than the unit specific installation dates for the installation and operation of CEMS identified at paragraphs (b)(1)(ii), (iv) and (v) of this section, respectively.

(C) All CEMS associated with monitoring SO<sub>2</sub> at the following facilities: U.S. Steel Keetac, U.S. Steel Minntac, and Northshore Mining Company-Silver Bay, must be installed and operational no later than six months after May 12, 2016.

(D) All CEMS associated with monitoring SO<sub>2</sub> at the following facilities: Hibbing Taconite Company, United Taconite, and ArcelorMittal Minorca Mine, must be installed and operational no later than six months after May 12, 2016.

(E) The operational status of the CEMS identified in paragraphs (c)(1) and (2) of this section shall be verified by, as a minimum, completion of the manufacturer's written requirements or recommendations for installation, operation, and calibration of the devices.

(iii) The owner or operator must conduct a performance evaluation of each CEMS in accordance with 40 CFR part 60, appendix B, PS-2. The performance evaluations must be completed no later than 60 days after the respective CEMS installation.

(iv) The owner or operator of each CEMS must conduct periodic Quality Assurance, Quality Control (QA/QC) checks of each CEMS in accordance with 40 CFR part 60, appendix F, Procedure 1. The first CEMS accuracy test will be a relative accuracy test audit (RATA) and must be completed no later than 60 days after the respective CEMS installation.

(v) The owner or operator of each CEMS must furnish the Regional Administrator two, or upon request, more copies of a written report of the results of each performance evaluation and QA/QC check within 60 days of completion.

(vi) The owner or operator of each CEMS must check, record, and quantify the zero and span calibration drifts at least once daily (every 24 hours) in accordance with 40 CFR part 60, appendix F, Procedure 1, Section 4.

(vii) Except for CEMS breakdowns, repairs, calibration checks, and zero and span adjustments, all CEMS required by this section shall be in continuous operation during all periods of BART affected process unit operation, including periods of process unit startup, shutdown, and malfunction.

(viii) All CEMS required by this section must meet the minimum data requirements at paragraphs (c)(4)(viii)(A) through (C) of this section.

(A) Complete a minimum of one cycle of operation (sampling, analyzing, and data recording) for each successive 15-minute quadrant of an hour.

(B) Sample, analyze, and record emissions data for all periods of process operation except as described in paragraph (c)(4)(viii)(C) of this section.

(C) When emission data from CEMS are not available due to continuous monitoring system breakdowns, repairs, calibration checks, or zero and span adjustments, emission data must be obtained using other monitoring systems or emission estimation methods approved by the EPA. The other monitoring systems or emission estimation methods to be used must be incorporated into the monitoring plan required by this section and provide information such that emissions data are available for a minimum of 18 hours in each 24-hour period and at least 22 out of 30 successive unit operating days.

(ix) Owners or operators of each CEMS required by this section must reduce all data to 1-hour averages. Hourly averages shall be computed using all valid data obtained within the hour but no less than one data point in each 15-minute quadrant of an hour. Notwithstanding this requirement, an hourly average may be computed from at least two data points separated by a minimum of 15 minutes (where the unit operates for more than one quadrant in an hour) if data are unavailable as a result of performance of calibration, quality assurance, preventive maintenance activities, or backups of data from data acquisition and handling systems and recertification events.

(x) The 30-day rolling average emission rate determined from data derived from the CEMS required by this section (in lbs/MMBTU or lbs/hr depending on the emission standard selected) must be calculated in accordance with paragraphs (c)(4)(x)(A) through (F) of this section.

(A) Sum the total pounds of the pollutant in question emitted from the unit during an operating day and the previous 29 operating days.

(B) Sum the total heat input to the unit (in MMBTU) or the total actual hours of operation (in hours) during an operating day and the previous 29 operating days.

(C) Divide the total number of pounds of the pollutant in question emitted during the 30 operating days by the total heat input (or actual hours of operation depending on the emission limit selected) during the 30 operating days.

(D) For purposes of this calculation, an operating day is any day during which fuel is combusted in the BART affected unit regardless of whether pellets are produced. Actual hours of operation are the total hours a unit is firing fuel regardless of whether a complete 24-hour operational cycle occurs (*i.e.* if the furnace is firing fuel for only five hours during a 24-hour period, then the actual operating hours for that day are five. Similarly, total number of pounds of the pollutant in question for that day is determined only from the CEMS data for the five hours during which fuel is combusted.)

(E) If the owner or operator of the CEMS required by this section uses an alternative method to determine 30-day rolling averages, that method must be described in detail in the monitoring plan required by this section. The alternative method will only be applicable if the final monitoring plan and the alternative method are approved by EPA.

(F) A new 30-day rolling average emission rate must be calculated for each new operating day.

(xi) The 720-hour rolling average emission rate determined from data derived from the CEMS required by this section (in lbs/MMBTU) must be calculated in accordance with (c)(4)(xi)(A) through (C).

(A) Sum the total pounds of NO<sub>x</sub> emitted from the unit every hour and the previous (not necessarily consecutive) 719 hours for which that type of fuel (either natural gas or mixed coal and natural gas) was used.

(B) Sum the total heat input to the unit (in MMBTU) every hour and the previous (not necessarily consecutive) 719 hours for which that type of fuel (either natural gas or mixed coal and natural gas) was used.

(C) Divide the total number of pounds of NO<sub>x</sub> emitted during the 720 hours, as defined above, by the total heat input during the same 720 hour period. This calculation must be done separately for each fuel type (either for natural gas or mixed coal and natural gas).

(xii) Data substitution must not be used for purposes of determining compliance under this section.

(xiii) All CEMS data shall be reduced and reported in units of the applicable standard.

(xiv) A Quality Control Program must be developed and implemented for all CEMS required by this section in accordance with 40 CFR part 60, appendix F, Procedure 1, Section 3. The program will include, at a minimum, written procedures and operations for calibration checks, calibration drift adjustments, preventative maintenance,

data collection, recording and reporting, accuracy audits/procedures, periodic performance evaluations, and a corrective action program for malfunctioning CEMS.

(d) *Recordkeeping requirements.* (1)(i) Records required by this section must be kept in a form suitable and readily available for expeditious review.

(ii) Records required by this section must be kept for a minimum of five years following the date of creation.

(iii) Records must be kept on site for at least two years following the date of creation and may be kept offsite, but readily accessible, for the remaining three years.

(2) The owner or operator of the BART affected units must maintain the records at paragraphs (d)(2)(i) through (xi) of this section.

(i) A copy of each notification and report developed for and submitted to comply with this section including all documentation supporting any initial notification or notification of compliance status submitted according to the requirements of this section.

(ii) Records of the occurrence and duration of startup, shutdown, and malfunction of the BART affected units, air pollution control equipment, and CEMS required by this section.

(iii) Records of activities taken during each startup, shutdown, and malfunction of the BART affected unit, air pollution control equipment, and CEMS required by this section.

(iv) Records of the occurrence and duration of all major maintenance conducted on the BART affected units, air pollution control equipment, and CEMS required by this section.

(v) Records of each excess emission report, including all documentation supporting the reports, dates and times when excess emissions occurred, investigations into the causes of excess emissions, actions taken to minimize or eliminate the excess emissions, and preventative measures to avoid the cause of excess emissions from occurring again.

(vi) Records of all CEMS data including, as a minimum, the date, location, and time of sampling or measurement, parameters sampled or measured, and results.

(vii) All records associated with quality assurance and quality control activities on each CEMS as well as other records required by 40 CFR part 60, appendix F, Procedure 1 including, but not limited to, the quality control program, audit results, and reports submitted as required by this section.

(viii) Records of the NO<sub>x</sub> emissions during all periods of BART affected unit operation, including startup, shutdown,

and malfunction in the units of the standard. The owner or operator shall convert the monitored data into the appropriate unit of the emission limitation using appropriate conversion factors and F-factors. F-factors used for purposes of this section shall be documented in the monitoring plan and developed in accordance with 40 CFR part 60, appendix A, Method 19. The owner or operator may use an alternate method to calculate the NO<sub>x</sub> emissions upon written approval from EPA.

(ix) Records of the SO<sub>2</sub> emissions in lbs/MMBTUs or lbs/hr (based on CEMS data), depending on the emission standard selected, during all periods of operation, including periods of startup, shutdown, and malfunction, in the units of the standard.

(x) Records associated with the CEMS unit including type of CEMS, CEMS model number, CEMS serial number, and initial certification of each CEMS conducted in accordance with 40 CFR part 60, appendix B, Performance Specification 2 must be kept for the life of the CEMS unit.

(xi) Records of all periods of fuel oil usage as required at paragraph (b)(2)(vii) of this section.

(e) *Reporting requirements.* (1) All requests, reports, submittals, notifications, and other communications to the Regional Administrator required by this section shall be submitted, unless instructed otherwise, to the Air and Radiation Division, U.S. Environmental Protection Agency, Region 5 (A-18J), at 77 West Jackson Boulevard, Chicago, Illinois 60604.

(2) The owner or operator of each BART affected unit identified in this section and CEMS required by this section must provide to the Regional Administrator the written notifications, reports and plans identified at paragraphs (e)(2)(i) through (viii) of this section. If acceptable to both the Regional Administrator and the owner or operator of each BART affected unit identified in this section and CEMS required by this section the owner or operator may provide electronic notifications, reports, and plans.

(i) A notification of the date construction of control devices and installation of burners required by this section commences postmarked no later than 30 days after the commencement date.

(ii) A notification of the date the installation of each CEMS required by this section commences postmarked no later than 30 days after the commencement date.

(iii) A notification of the date the construction of control devices and installation of burners required by this

section is complete postmarked no later than 30 days after the completion date.

(iv) A notification of the date the installation of each CEMS required by this section is complete postmarked no later than 30 days after the completion date.

(v) A notification of the date control devices and burners installed by this section startup postmarked no later than 30 days after the startup date.

(vi) A notification of the date CEMS required by this section startup postmarked no later than 30 days after the startup date.

(vii) A notification of the date upon which the initial CEMS performance evaluations are planned. This notification must be submitted at least 60 days before the performance evaluation is scheduled to begin.

(viii) A notification of initial compliance, signed by the responsible official who shall certify its accuracy, attesting to whether the source has complied with the requirements of this section, including, but not limited to, applicable emission standards, control device and burner installations, CEMS installation and certification. This notification must be submitted before the close of business on the 60th calendar day following the completion of the compliance demonstration and must include, at a minimum, the information at paragraphs (e)(2)(viii)(A) through (F) of this section.

(A) The methods used to determine compliance.

(B) The results of any CEMS performance evaluations, and other monitoring procedures or methods that were conducted.

(C) The methods that will be used for determining continuing compliance, including a description of monitoring and reporting requirements and test methods.

(D) The type and quantity of air pollutants emitted by the source, reported in units of the standard.

(E) A description of the air pollution control equipment and burners installed as required by this section, for each emission point.

(F) A statement by the owner or operator as to whether the source has complied with the relevant standards and other requirements.

(3) The owner or operator must develop and implement a written startup, shutdown, and malfunction plan for NO<sub>x</sub> and SO<sub>2</sub>. The plan must include, at a minimum, procedures for operating and maintaining the source during periods of startup, shutdown, and malfunction; and a program of corrective action for a malfunctioning process and air pollution control and

monitoring equipment used to comply with the relevant standard. The plan must ensure that, at all times, the owner or operator operates and maintains each affected source, including associated air pollution control and monitoring equipment, in a manner which satisfies the general duty to minimize or eliminate emissions using good air pollution control practices. The plan must ensure that owners or operators are prepared to correct malfunctions as soon as practicable after their occurrence.

(4) The written reports of the results of each performance evaluation and QA/QC check in accordance with and as required by paragraph (c)(4)(v) of this section.

(5) *Compliance reports.* The owner or operator of each BART affected unit must submit semiannual compliance reports. The semiannual compliance reports must be submitted in accordance with paragraphs (e)(5)(i) through (iv) of this section, unless the Administrator has approved a different schedule.

(i) The first compliance report must cover the period beginning on the compliance date that is specified for the affected source through June 30 or December 31, whichever date comes first after the compliance date that is specified for the affected source.

(ii) The first compliance report must be postmarked no later than 30 calendar days after the reporting period covered by that report (July 30 or January 30), whichever comes first.

(iii) Each subsequent compliance report must cover the semiannual reporting period from January 1 through June 30 or the semiannual reporting period from July 1 through December 31.

(iv) Each subsequent compliance report must be postmarked no later than 30 calendar days after the reporting period covered by that report (July 30 or January 30).

(6) *Compliance report contents.* Each compliance report must include the information in paragraphs (e)(6)(i) through (vi) of this section.

(i) Company name and address.

(ii) Statement by a responsible official, with the official's name, title, and signature, certifying the truth, accuracy, and completeness of the content of the report.

(iii) Date of report and beginning and ending dates of the reporting period.

(iv) Identification of the process unit, control devices, and CEMS covered by the compliance report.

(v) A record of each period of startup, shutdown, or malfunction during the reporting period and a description of the actions the owner or operator took to

minimize or eliminate emissions arising as a result of the startup, shutdown or malfunction and whether those actions were or were not consistent with the source's startup, shutdown, and malfunction plan.

(vi) A statement identifying whether there were or were not any deviations from the requirements of this section during the reporting period. If there were deviations from the requirements of this section during the reporting period, then the compliance report must describe in detail the deviations which occurred, the causes of the deviations, actions taken to address the deviations, and procedures put in place to avoid such deviations in the future. If there were no deviations from the requirements of this section during the reporting period, then the compliance report must include a statement that there were no deviations. For purposes of this section, deviations include, but are not limited to, emissions in excess of applicable emission standards established by this section, failure to continuously operate an air pollution control device in accordance with operating requirements designed to assure compliance with emission standards, failure to continuously operate CEMS required by this section, and failure to maintain records or submit reports required by this section.

(7) Each owner or operator of a CEMS required by this section must submit quarterly excess emissions and monitoring system performance reports for each pollutant monitored for each BART affected unit monitored. All reports must be postmarked by the 30th day following the end of each three-month period of a calendar year (January-March, April-June, July-September, October-December) and must include, at a minimum, the requirements at paragraphs (e)(7)(i) through (xv) of this section.

(i) Company name and address.

(ii) Identification and description of the process unit being monitored.

(iii) The dates covered by the reporting period.

(iv) Total source operating hours for the reporting period.

(v) Monitor manufacturer, monitor model number, and monitor serial number.

(vi) Pollutant monitored.

(vii) Emission limitation for the monitored pollutant.

(viii) Date of latest CEMS certification or audit.

(ix) A description of any changes in continuous monitoring systems, processes, or controls since the last reporting period.

(x) A table summarizing the total duration of excess emissions, as defined at paragraphs (e)(7)(x)(A) through (B) of this section, for the reporting period broken down by the cause of those excess emissions (startup/shutdown, control equipment problems, process problems, other known causes, unknown causes), and the total percent of excess emissions (for all causes) for the reporting period calculated as described at paragraph (e)(7)(x)(C) of this section.

(A) For purposes of this section, an excess emission is defined as any 30-day or 720-hour rolling average period, including periods of startup, shutdown, and malfunction, during which the 30-day or 720-hour (as appropriate) rolling average emissions of either regulated pollutant (SO<sub>2</sub> and NO<sub>x</sub>), as measured by a CEMS, exceeds the applicable emission standards in this section.

(B)(1) For purposes of this rule, if a facility calculates a 30-day rolling average emission rate in accordance with this rule which exceeds the applicable emission standards of this rule, then it will be considered 30 days of excess emissions. If the following 30-day rolling average emission rate is calculated and found to exceed the applicable emission standards of this rule as well, then it will add one more day to the total days of excess emissions (*i.e.* 31 days). Similarly, if an excess emission is calculated for a 30-day rolling average period and no additional excess emissions are calculated until 15 days after the first, then that new excess emission will add 15 days to the total days of excess emissions (*i.e.* 30 + 15 = 45). For purposes of this section, if an excess emission is calculated for any period of time within a reporting period, there will be no fewer than 30 days of excess emissions but there should be no more than 121 days of excess emissions for a reporting period.

(2) For purposes of this section, if a facility calculates a 720-hour rolling average emission rate in accordance with this rule which exceeds the applicable emission standards of this section, then it will be considered 30 days of excess emissions. If the 24th following 720-hour rolling average emission rate is calculated and found to exceed the applicable emission standards of the rule as well, then it will add one more day to the total days of excess emissions (*i.e.* 31 days). Similarly, if an excess emission is calculated for a 720-hour rolling average period and no additional excess emissions are calculated until 360 hours after the first, then that new excess emission will add 15 days to the total days of excess emissions (*i.e.* 30+15 =

45). For purposes of this section, if an excess emission is calculated for any period of time with a reporting period, there will be no fewer than 30 days of excess emissions but there should be no more than 121 days of excess emissions for a reporting period.

(C) For purposes of this section, the total percent of excess emissions will be determined by summing all periods of excess emissions (in days) for the reporting period, dividing that number by the total BART affected unit operating days for the reporting period, and then multiplying by 100 to get the total percent of excess emissions for the reporting period. An operating day, as defined previously, is any day during which fuel is fired in the BART affected unit for any period of time. Because of the possible overlap of 30-day rolling average excess emissions across quarters, there are some situations where the total percent of excess emissions could exceed 100 percent. This extreme situation would only result from serious excess emissions problems where excess emissions occur for nearly every day during a reporting period.

(xi) A table summarizing the total duration of monitor downtime, as defined at paragraph (e)(7)(xi)(A) of this section, for the reporting period broken down by the cause of the monitor downtime (monitor equipment malfunctions, non-monitor equipment malfunctions, quality assurance calibration, other known causes, unknown causes), and the total percent of monitor downtime (for all causes) for the reporting period calculated as described at paragraph (e)(7)(xi)(B) of this section.

(A) For purposes of this section, monitor downtime is defined as any period of time (in hours) during which the required monitoring system was not measuring emissions from the BART affected unit. This includes any period of CEMS QA/QC, daily zero and span checks, and similar activities.

(B) For purposes of this section, the total percent of monitor downtime will be determined by summing all periods of monitor downtime (in hours) for the reporting period, dividing that number by the total number of BART affected unit operating hours for the reporting period, and then multiplying by 100 to get the total percent of excess emissions for the reporting period.

(xii) A table which identifies each period of excess emissions for the reporting period and includes, at a minimum, the information in paragraphs (e)(7)(xii)(A) through (F) of this section.

(A) The date of each excess emission.

(B) The beginning and end time of each excess emission.

(C) The pollutant for which an excess emission occurred.

(D) The magnitude of the excess emission.

(E) The cause of the excess emission.

(F) The corrective action taken or preventative measures adopted to minimize or eliminate the excess emissions and prevent such excess emission from occurring again.

(xiii) A table which identifies each period of monitor downtime for the reporting period and includes, at a minimum, the information in paragraphs (e)(7)(xiii)(A) through (D) of this section.

(A) The date of each period of monitor downtime.

(B) The beginning and end time of each period of monitor downtime.

(C) The cause of the period of monitor downtime.

(D) The corrective action taken or preventative measures adopted for system repairs or adjustments to minimize or eliminate monitor downtime and prevent such downtime from occurring again.

(xiv) If there were no periods of excess emissions during the reporting period, then the excess emission report must include a statement which says there were no periods of excess emissions during this reporting period.

(xv) If there were no periods of monitor downtime, except for daily zero and span checks, during the reporting period, then the excess emission report must include a statement which says there were no periods of monitor downtime during this reporting period except for the daily zero and span checks.

(8) The owner or operator of each CEMS required by this section must develop and submit for review and approval by the Regional Administrator a site specific monitoring plan. The purpose of this monitoring plan is to establish procedures and practices which will be implemented by the owner or operator in its effort to comply with the monitoring, recordkeeping, and reporting requirements of this section. The monitoring plan must include, at a minimum, the information at paragraphs (e)(8)(i) through (x) of this section.

(i) Site specific information including the company name, address, and contact information.

(ii) The objectives of the monitoring program implemented and information describing how those objectives will be met.

(iii) Information on any emission factors used in conjunction with the

CEMS required by this section to calculate emission rates and a description of how those emission factors were determined.

(iv) A description of methods to be used to calculate emission rates when CEMS data are not available due to downtime associated with QA/QC events.

(v) A description of the QA/QC program to be implemented by the owner or operator of CEMS required by this section. This can be the QA/QC program developed in accordance with 40 CFR part 60, appendix F, Procedure 1, Section 3.

(vi) A list of spare parts for CEMS maintained on site for system maintenance and repairs.

(vii) A description of the procedures to be used to calculate 30-day rolling averages and 720-hour rolling averages and example calculations which show the algorithms used by the CEMS to calculate 30-day rolling averages and 720-hour rolling averages.

(viii) A sample of the document to be used for the quarterly excess emission reports required by this section.

(ix) A description of the procedures to be implemented to investigate root causes of excess emissions and monitor downtime and the proposed corrective actions to address potential root causes of excess emissions and monitor downtime.

(x) A description of the sampling and calculation methodology for determining the percent sulfur by weight as a monthly block average for coal used during that month.

(f) *Equations for establishing the upper predictive limit—(1) Equation for normal distribution and statistically independent data.*

$$UPL = \bar{x} + t_{[(n-1),(0.95)]} \sqrt{s^2 \left( \frac{1}{n} + \frac{1}{m} \right)}$$

Where:

$\bar{x}$  = average or mean of hourly test run data;  
 $t_{[(n-1),(0.95)]}$  = t score, the one-tailed t value of the Student's t distribution for a specific degree of freedom (n - 1) and a confidence level (0.95; 0.99 for Tilden SO<sub>2</sub>)

$s^2$  = variance of the hourly data set;  
 $n$  = number of values (e.g. 5,760 if 8 months of valid lbs NO<sub>x</sub>/MMBTU hourly values)  
 $m$  = number of values used to calculate the test average (m = 720 as per averaging time)

(i) To determine if statistically independent, use the Rank von Neumann Test on p. 137 of data Quality Assessment: Statistical Methods for Practitioners EPA QA/G-9S.

(ii) Alternative to Rank von Neumann test to determine if data are dependent, data are dependent if t test value is greater than t critical value, where:

$$t \text{ test} = \frac{\rho}{\sqrt{\frac{1 - \rho^2}{n - 2}}}$$

$\rho$  = correlation between data points  
 $t \text{ critical} = t_{[(n-2),(0.95)]}$  = t score, the two-tailed t value of the Student's t distribution for a specific degree of freedom (n - 2) and a confidence level (0.95)

(iii) The Anderson-Darling normality test is used to establish whether the data are normally distributed. That is, a distribution is considered to be normally distributed when  $p > 0.05$ .

(2) *Non-parametric equation for data not normally distributed and normally distributed but not statistically independent.*

$$m = (n + 1) * \alpha$$

$m$  = the rank of the ordered data point, when data are sorted smallest to largest. The data points are 720-hour averages for establishing NO<sub>x</sub> limits.

$n$  = number of data points (e.g., 5040 720-hourly averages for eight months of valid NO<sub>x</sub> lbs/MMBTU values)

$\alpha = 0.95$ , to reflect the 95th percentile

If  $m$  is a whole number, then the limit, UPL, shall be computed as:

$$UPL = X_m$$

Where:

$X_m$  = value of the  $m$ th data point in terms of lbs SO<sub>2</sub>/hr or lbs NO<sub>x</sub>/MMBTU, when the data are sorted smallest to largest.

If  $m$  is not a whole number, the limit shall be computed by linear interpolation according to the following equation.

$$UPL = X_m = X_{m_i; m_d} = X_{m_i} + 0.m_d (X_{m_i + 1} - X_{m_i})$$

Where:

$m_i$  = the integer portion of  $m$ , i.e.,  $m$  truncated at zero decimal places, and  
 $m_d$  = the decimal portion of  $m$

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